

**A COMPARATIVE STUDY OF SINGLE DOSE VERSUS MULTI  
DOSE THERAPY FOR TREATMENT OF ASYMPTOMATIC  
BACTERIURIA IN PREGNANCY AND STUDY OF PREVALENCE  
AND ASSOCIATED RISK FACTORS OF ASYMPTOMATIC  
BACTERIURIA IN ANTENATAL WOMEN IN KILPAUK  
MEDICAL COLLEGE & HOSPITAL**

*Submitted to*

*The Tamil Nadu Dr. M.G.R. Medical University*

*In partial fulfillment of the requirements for the award of the degree of*

**M.D. DEGREE EXAMINATION  
BRANCH – II (OBSTETRICS & GYNAECOLOGY)**



**KILPAUK MEDICAL COLLEGE  
THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY  
CHENNAI**

**APRIL 2013**

## **BONAFIDE CERTIFICATE**

Certified that the dissertation titled **“A Comparative study of single dose versus multi dose therapy for treatment of asymptomatic bacteriuria in pregnancy and study of prevalence and associated risk factors of asymptomatic bacteriuria in antenatal women in Kilpauk Medical College & Hospital”** is a bonafide work of the candidate **Dr.R.HARINI**, post graduate student, Department of Obstetrics & Gynecology, Kilpauk Medical College, Chennai – 10, done under my guidance and supervision, in partial fulfillment of regulations of **The Tamilnadu Dr.MGR Medical University** for the award of **M.D. Degree Branch II, (Obstetrics & Gynecology)** during the academic period from May 2010 to April 2013.

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## DECLARATION

I **Dr. R.HARINI** solemnly declare that this dissertation  
“**A Comparative study of single dose versus multi dose therapy for  
treatment of asymptomatic bacteriuria in pregnancy and study of  
prevalence and associated risk factors of asymptomatic bacteriuria in  
antenatal women in Kilpauk Medical College & Hospital**” was prepared  
by me at Government Kilpauk Medical College and Hospital, Chennai,  
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This dissertation is submitted to **The Tamil Nadu Dr. M.G.R.  
Medical University, Chennai** in partial fulfillment of the University  
regulations for the award of the degree of **M.D. Branch II (Obstetrics and  
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Place : Chennai  
Date :

**(Dr. R.HARINI)**

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**Dr.R.Harini**

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## ANNEXURES

- ❖ BIBLIOGRAPHY
- ❖ PROFORMA
- ❖ MASTER CHART
- ❖ ETHICAL COMMITTEE APPROVAL
- ❖ CONSENT FORM

## **ABBREVIATIONS USED**

UTI – Urinary Tract Infection

ASB – Asymptomatic bacteriuria

E.Coli – Escherichia Coli

BMI – Body Mass Index

ACOG – American College of Obstetricians and Gynecologists

GFR – Glomerular Filtration Rate

H/O – History of

CLED – Cysteine Lactose Electrolyte Deficient

H<sub>2</sub>O<sub>2</sub> - Hydrogen peroxide

WHMC – Winston Hills Medical Centre

LBW – Low Birth Weight

CFU – Colony Forming Units

spp. – species

qid – four times daily

bd – twice daily

RR – Relative risk

CI – Confidence Interval

KMCH - Kilpauk Medical College Hospital

C/S – Culture and Sensitivity



## INTRODUCTION

Urinary tract infection is the infection of the so called 'The Problem Tract', that is the tract which goes down from the kidney to the urethra is one of the place where infections are most common, next only to respiratory tract. The importance of the urinary tract infection is best realized, in the wake of its perilous complications.

Mostly bacterial infections are common. In that, urinary tract infection caused by occur more frequently in women more so in pregnant women due to normal functional changes and changes that change the morphology that takes place during pregnancy, in the genitourinary tract. UTI is divided into two types. It can be either symptomatic or asymptomatic. Early detecting and treating of ASB is of considerable importance to reduce the mortality and morbidity in the mother and offspring.

Asymptomatic bacteriuria is commonly referred as significant bacteriuria in the non existence of any specific symptoms of infection. Its incidence is found to be in 2% - 10% of all pregnant women ( Whalley 1967 ).

The previously defined criteria for labeling it as asymptomatic bacteriuria was the presence of  $> 10^5$  bacteria/ml in two clean catch samples taken on two consecutive days (Kass 1960a). But then, the finding of  $> 10^5$  bacterial/ml in a single voided midstream urine sample seems to be a

satisfactory as well as a more practical alternative, although the chance that the woman has bacteriuria with single sample is only 80%. It increases to 95% if more than two consecutive cultures collected show the presence of the same organism (Kass 1960a). Though, in pregnancy, there are urine screening tests which detect rapidly, since the end results are not reliable, quantitative urine culture is always the gold standard for detecting asymptomatic bacteriuria.

Bacteriuria which occurs in pregnancy has greater chances to end up in pyelonephritis in up to 40 percent of pregnant women than during nonpregnant period. Pregnant women who had had asymptomatic bacteriuria (ASB) are also more likely to develop Hypertensive disorders of pregnancy, Anemia, Chronic renal failure and UTI postpartum if untreated. So the incidence of these deadly complications can be decreased by promptly diagnosing asymptomatic bacteriuria during pregnancy and treating it early.

Urinary tract infection can also result in increased rates of preterm labour, low birth weight babies, and increased perinatal mortality. Treating bacteriuria in pregnancy reduces the occurrence of these complications, thus preventing the long term sequel that follows asymptomatic bacteriuria.

Screening for asymptomatic bacteriuria and prompt management of asymptomatic bacteriuria in pregnancy has become a standard protocol in modern obstetric care.

Treatment of bacteriuria alone prevents up to 80 percent of cases progressing to pyelonephritis. Numerous studies have shown that single-dose antibiotic treatment for asymptomatic bacteriuria in pregnancy is as effective as long course treatments. Single-dose treatment, which is equally effective to long course treatment, also has the advantages of minimal medication, increased patient compliance, cost-effectiveness, reduced side-effects and increased safety.

Considering the above factors, the present study is designed to analyse the prevalence of asymptomatic bacteriuria in pregnant women and the associated risk factors and to compare the efficacy of single dose to conventional treatment of asymptomatic bacteriuria.

# **REVIEW OF LITERATURE**

This is discussed under the following headings:

- HISTORY
- EPIDEMIOLOGY
- EMBRYOLOGY OF URINARY TRACT
- ANATOMY OF URINARY TRACT:
- MORPHOLOGICAL AND FUNCTIONAL CHANGES TAKING PLACE IN THE URINARY TRACT IN PREGNANCY
- PREDISPOSING FACTORS FOR ASYMPTOMATIC BACTERIURIA
- NORMAL FLORA OF THE GENITOURINARY TRACT
- URINARY TRACT INFECTIONS
- MICROBIOLOGY
- PATHOGENESIS OF URINARY TRACT INFECTION
- COMPLICATIONS ASSOCIATED WITH ASYMPTOMATIC BACTERIURIA OF PREGNANCY
- DIAGNOSIS
- TREATMENT

## **HISTORY:**

In 1550 BC, Hearst Papyrus stated “sending forth heat from the bladder” as a way to refer to the urinary tract infection<sup>1</sup>.

Pasteur (1863) discovered urine to be a good culture medium for bacterial growth and Roberts (1881) correlated the bacteria presence in the urine to the symptoms but very little progress was made in exploring this relationship until quantitative assessments of the number of bacteria in the urine of patients with urinary tract infection were carried out by Marple (1941), Barr and Rantz (1948) and Sanford et al (1956)<sup>2</sup>.

In 1957, Kass, through his pioneer work in this field established the validity of quantitative urine culture and documented that significant bacteriuria can occur in the absence of symptoms or signs of UTI<sup>3,4</sup>. The initial observations that ASB contributes to chronic renal failure, hypertension, and toxemia of pregnancy, generated a series of population based screening programs for ASB<sup>5</sup>.

## **HISTORY OF ORGANISMS ISOLATED COMMONLY IN ASYMPTOMATIC BACTERIURIA**

In 1885, German Pediatrician Theodore Escherichia first identified E. coli.

In 1919, Castellani and Chalmers identified the genus *Escherichia* and defined the species type *E. coli*<sup>1</sup>.

In 1983, Friedlander first isolated this bacillus from fatal cases of pneumonia, also known to cause UTI.<sup>1,6</sup>

In 1880, Sir Alexander Ogston, a Scottish surgeon gave the name *Staphylococcus*.<sup>1</sup>

In 1884, Rosenbach first described the genus as *Staphylococcus* and split the genus into two types of species, namely *Staphylococcus aureus* and *Staphylococcus albus*.<sup>7</sup>

In 1965, Baird-Parker, recognised the species *Staphylococcus aureus*, *Staphylococcus epidermidis* and *Staphylococcus saprophyticus*.<sup>1</sup>

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## **EPIDEMIOLOGY:**

Asymptomatic bacteriuria results in various complications which affects the fetus and is one of the causes of medical complications of

pregnancy. In 1962 when pregnant women with bacteriuria were compared with pregnant women without bacteriuria, Edward Kass found that 6% of antenatal women having ASB were associated with higher rates of delivery of premature babies and perinatal mortality.<sup>8</sup>

Prevalence of ASB in the obstetric population ranges from 3-10%.<sup>9</sup>

The prevalence of ASB was found 8.4% in a study in Vishakhapatnam, India during the year 1997 to 1999. Primigravida had highest percent culture positivity of 66.6%. This study, revealed that incidence increased as socio-economic status of the patients decreased and higher incidence was recorded in patients of lower age group (<20 years age group i.e. 71.42%). Most commonly, E. coli was the microorganism isolated (83.3%).<sup>10</sup>

In a study in Nigeria, they found high incidence of bacteriuria during third trimester of pregnancy (21.9%) compared with that in the first trimester (77%) while the level in the second trimester was 22.5%. Staphylococcus aureus was the most frequent pathogen (41.3%).<sup>11</sup>

Another study was done which identified the fact that prevalence of ASB in the diabetic antenatal women was 12.5% as compared to 5.9% of the normal pregnancies.<sup>12</sup>

A study conducted on 270 pregnant women found prevalence of ASB was 9.3% and sensitivity and specificity of leukocyturia as a screening test was 91.3% and 83.6%.<sup>13</sup>

The risk of ASB was found to be 0.8% in first trimester which increased to 1.93% at term. So risk increases as pregnancy advances.<sup>14</sup>

In a study performed in Turkey, prevalence of ASB in the first trimester was 0.9%, in the second trimester was 1.83% and in the third trimester was 5.6%.<sup>15</sup>

In 1997, a study on pregnant women aged between 15-40 years showed E.coli was found in 46% followed by coagulase negative Staphylococci (33%) and Citrobacter freundii (8%). Anti-microbial susceptibility test revealed 91% of E.coli isolated was resistant to ampicillin and amoxycillin and 91% of them sensitive to nitrofurantoin.<sup>16</sup>

One study to determine rates of occurrence of bacteriuria according to different races in London, demonstrated that, in the Caucasian group, the prevalence of bacteriuria was 6.3% and the prevalence is 2% for the Bangladeshi women.<sup>17</sup>



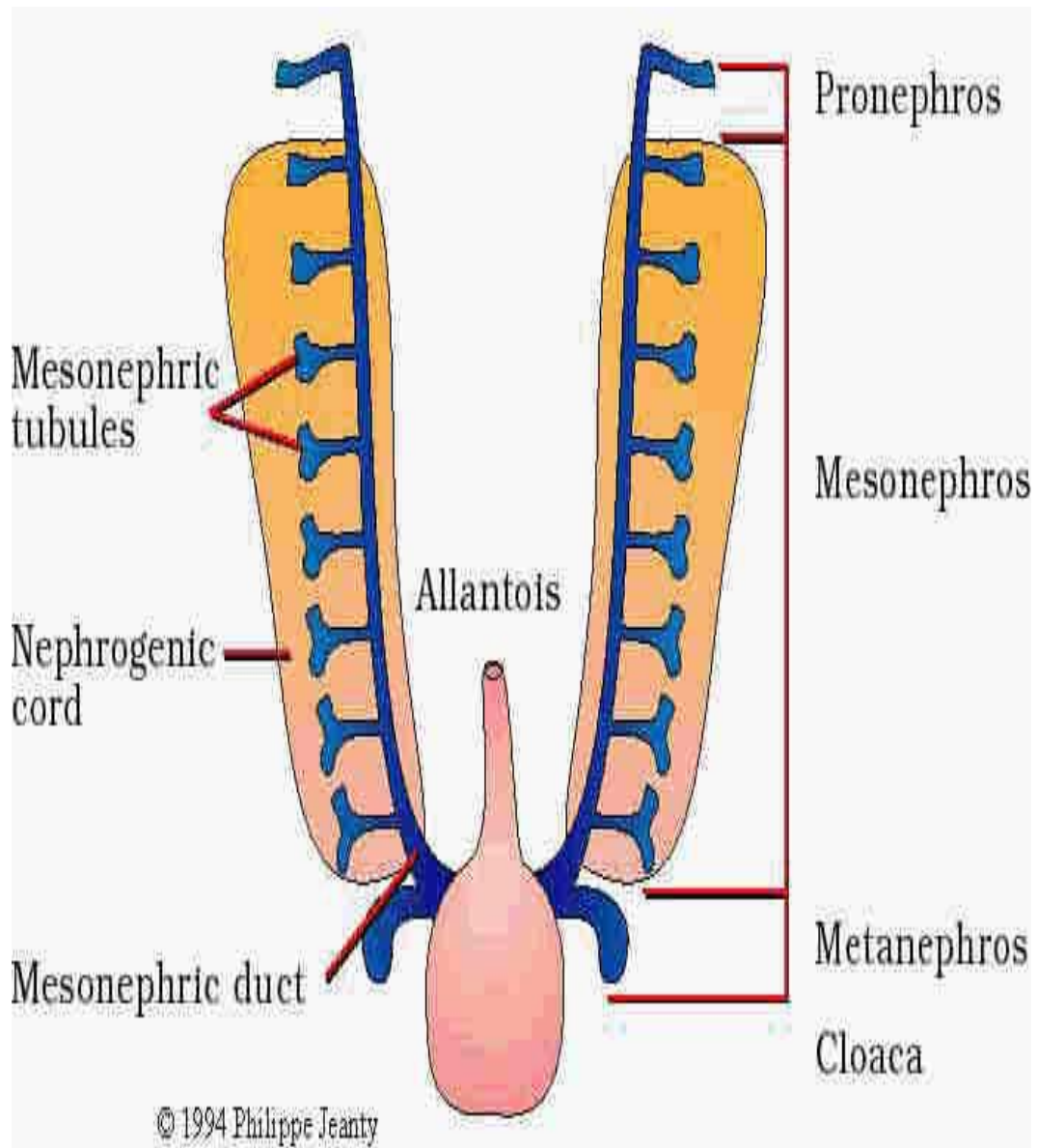
Another study which was done retrospectively in 24,000 births showed that the prevalence of bacteriuria in pregnancy was 28.7% in Whites and Asians, and 30% in Black and 41.1% in Hispanics.<sup>18</sup>

The prevalence of ASB in a study at Iran on 1100 pregnant women was 6.1%. Maternal age was lower in the women with a positive urine culture ( $p=0.02$ ). ASB did not have any significant relation with the trimester of the pregnancy ( $p=0.53$ ), parity ( $p=0.84$ ), the level of education ( $p=0.52$ ) and the BMI ( $p=0.17$ ).<sup>9</sup>

A study by the ACOG showed that on comparing different strategies of screening like leukocyte esterase-nitrite dipstick or urine culture and various treatment modalities it was concluded that culture techniques were not cost beneficial as compared to the dipstick technique.<sup>20</sup>

A study at Middlesex, England concluded that the conditions which favoured upon the cost effectiveness of screening for ASB in pregnancy was decided by the local population's characteristics, and more specifically by the prevalence of ASB in pregnancy.<sup>21</sup>

## EMBRYOLOGY OF URINARY TRACT:<sup>22</sup>



## UROGENITAL SYSTEM:

Urogenital system is derived from the intermediate mesoderm, and the primitive urogenital sinus which is a part of cloaca.

**KIDNEYS:**

Kidneys develop from two sources. The nephrons are derived from the metanephros. The collecting part is formed by ramification of the ureteric bud.

**URETER:**

Ureter arises from the ureteric bud.

**URINARY BLADDER:**

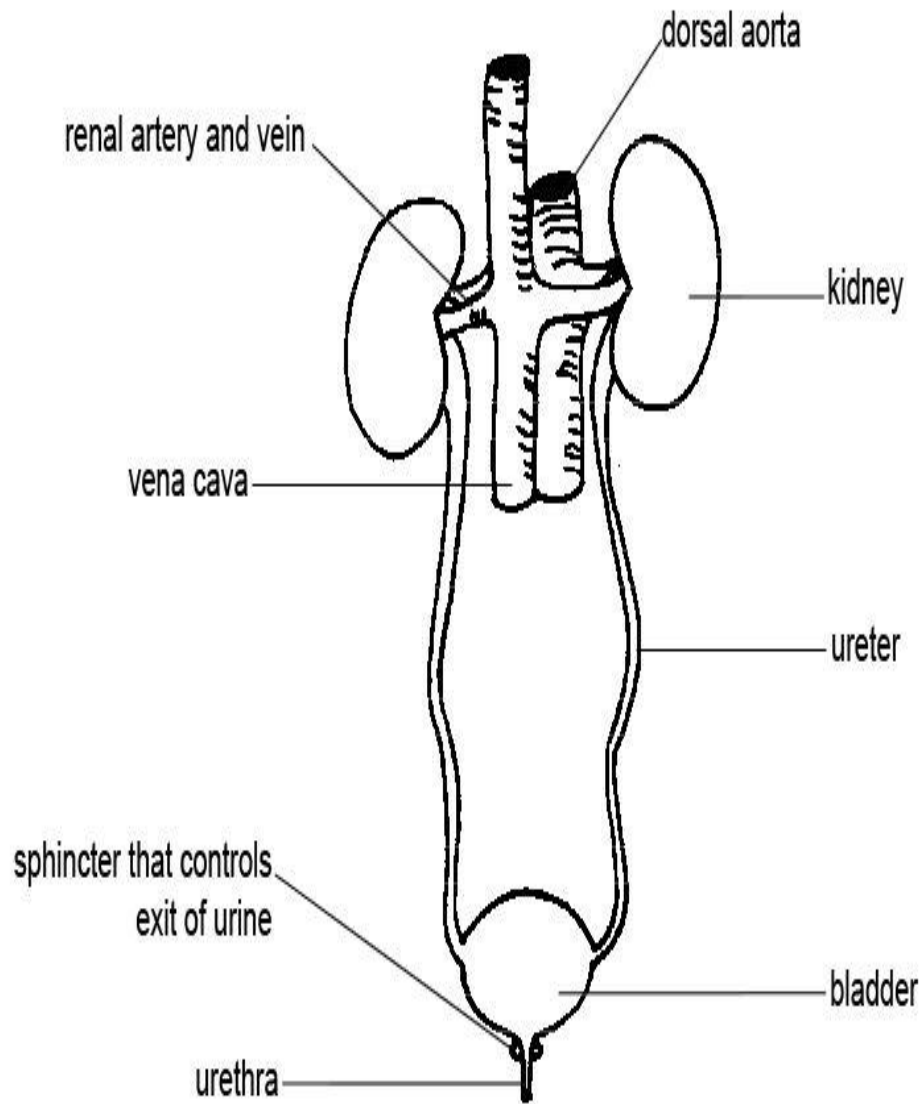
Urinary bladder is derived from the cranial part of the vesicourethral canal. Trigone epithelium is derived from absorbed mesonephric ducts.

**FEMALE URETHRA:**

The female urethra is derived from the primitive urethra and the pelvic part of the urogenital system.

## ANATOMY OF URINARY TRACT:

The urinary tract consists of kidney, urinary bladder, ureter and urethra



**KIDNEYS:**

2 in numbers, it measures in dimensions in length 11 cm, in breadth 6 cm and thickness 3 cm. Left kidney is slightly longer and narrower than the right kidney. On an average it weighs 150 gms in males and 135 gms in females. Blood supply is by a pair of renal arteries from aorta. Venous drainage is by a pair of renal veins which drain into inferior vena cava. Lymphatic drainage is to lateral aortic lymph nodes. Nerve supply is by renal sympathetic plexus.

**URETERS:**

Each ureter is about 25 cms long- 10 inches. Half of the ureter- 5 inches lies in the abdomen and half of the ureter- remaining 5 inches lies in the pelvis. In diameter, it measures about 3 cm. There are 3 constrictions in the ureter. Upper third of the ureter is supplied by renal arteries, and the middle third by testicular or ovarian artery and the last third by superior vesical artery. Venous drainage is by corresponding veins. Lymphatic drainage is to lateral aortic and iliac nodes. Nerve supply is by renal, testicular or ovarian and hypogastric nerves.

**URINARY BLADDER:**

It is a distensible organ which has varied size and shape according to the amount of urine it contains. Branches of internal iliac artery-superior and inferior vesical arteries supply urinary bladder. Vesical venous plexus drain into the internal iliac vein. Lymphatic drainage is into the iliac nodes and from there to the para aortic nodes. Sympathetic and parasympathetic fibres from the inferior hypogastric plexus innervate the bladder.

**FEMALE URETHRA:**

Female urethra is 4 cm long and 6mm in diameter. Vesical and principally the vaginal artery supply the female urethra. Veins draining the urethra drain into vesical plexus of veins and the internal pudendal veins. Lymphatics drain into internal and external iliac nodes. Fibres supplying urethra come from inferior hypogastric plexus and the perineal branch of pudendal nerve.

## **MORPHOLOGICAL AND FUNCTIONAL CHANGES TAKING PLACE IN THE URINARY TRACT IN PREGNANCY:<sup>23</sup>**

### **ANATOMICAL CHANGES:**

#### **KIDNEY-**

There is dilatation of the ureter and the renal pelvis. The kidneys enlarge in size by 1 cm.

#### **URETER-**

Ureters become atonic due to high progesterone level. Dilatation of the ureter above the pelvic brim with stasis is more marked on the right side especially in primigravida. It is due to dextrorotation of the uterus pressing the right ureter against the pelvic brim and also due to pressure by the right ovarian vein which crosses the right ureter at right angle. The stasis is more marked between 20-24 weeks. There is marked hypertrophy of the muscle and the sheath of the ureter specially of the pelvic part probably due to estrogen. There is elongation, kinking and outward displacement of the ureters.

#### **BLADDER-**

There is marked congestion and hypertrophy of the muscles and elastic tissues of the wall. In late pregnancy, the bladder mucosa becomes

oedematous due to venous and lymphatic obstruction especially in primigravida following early engagement. Increased frequency of micturition is noticed at 6-8 weeks of pregnancy which subsides after 12 weeks. It may be due to resetting of osmoregulation causing increased water intake and polyuria. In late pregnancy, frequency of micturition once more reappears due to pressure on the bladder as the presenting part descends down the pelvis. Stress incontinence may be observed in late pregnancy due to urethral sphincter weakness.

## **FUNCTIONAL CHANGES:**

### **Renal changes:**

Renal blood flow increases by about 80% by the second trimester, but falls in the third trimester. Therefore, there is corresponding increase in the glomerular filtration rate (50%), although less than the renal blood flow. Hence, creatinine clearance also increases. In pregnancy major changes in tubular reabsorption occurs.

### **Serum creatinine:**

Serum creatinine levels fall in pregnancy as the renal clearance is inversely proportional to the plasma concentration. Levels above 0.8 mg/dl are suggestive of intrinsic renal disease.



**Serum urea and uric acid:**

Serum urea and uric acid levels also decrease in pregnancy due to the increased renal clearance and defective tubular reabsorption. Normal levels are 15-20mg/dl. In late pregnancy, serum uric acid increases due to the decreasing GFR and due to the gradual increase in tubular reabsorption, but the level is always less than the normal values.

**Glycosuria:**

Glucose is completely reabsorbed in the non- pregnant state so that no glucose appears in urine in healthy individuals. In pregnancy, however many women with normal blood sugar may exhibit glycosuria. The remarkable increase in glomerular filtration along with the defective tubular reabsorption of glucose results in lowering of the renal threshold in pregnancy (normal is 180mg/dl) and this results in glycosuria without concomitant increase in blood sugar.

**Proteinuria:**

Proteinuria-5% of pregnant women may show orthostatic or postural proteinuria when the women is ambulatory. This is normal in the absence of renal disease. Significant proteinuria is abnormal and considered as more than 300mg in 24 hours.

## **PREDISPOSING FACTORS FOR ASYMPTOMATIC BACTERIURIA**

Sexual activity, increasing age, parity, sickle cell disease or trait (with associated renal parenchymal damage), low socioeconomic status, a H/O of UTIs, diabetes mellitus and anatomic abnormalities that in both the pregnant and non-pregnant state are associated with an increasing frequency of UTI.<sup>24</sup>

Women at high risk for recurrent UTIs may be more genetically prone to recurrent infections because they have a high prevalence of the human leukocyte.

Women of blood group B or AB who are nonsecretors of blood group substances are at significantly higher risk for developing infections, than are the women of other blood groups. In addition, patients with Lewis blood group types who are considered secretors have a lower incidence of urinary tract infections.<sup>25</sup>

In 1962, Tyagi, in his study found that 29.4% of primiparae and 21.7% of multiparae had asymptomatic bacteriuria.<sup>26</sup>

In 1965, Kass EH, Savage WB, Santamarina BAG in their study found that bacteriuria was somewhat more common among blacks than among whites.

In 1967, Savage et al. found that the prevalence of bacteriuria increased with age by 1% to 1.5% per decade and that the frequency of bacteriuria was directly proportional to gravidity.<sup>27</sup>

In 1974, Shanti Kumari Roy, GR Sinha, M Quadros in their study reported that the incidence of bacteriuria was found to increase slightly with increasing parity (11.6% in primigravidae as against 14.7% in grand multiparae) and the incidence of bacteriuria was found to be 10% in the first trimester to 13.1% in the third trimester. In their study they also found that 16.1% of 31 bacteriurics and 4.6% of 219 nonbacteriurics gave a past history of urinary tract infection.<sup>28</sup>

In 1977, P Mitra, VA Kulkarni, SR Sengupta et al. in their study found that the total incidence of bacteriuria was 10.3%, 6% at 28 weeks of gestation, with 4.5% developing bacteriuria at 36-38 weeks of pregnancy. 27.3% of bacteriuric patients belonged to < 20 years age group, 68.2% of bacteriuric patients belonged to 20 to 30 years and 4.5% of bacteriuric patients belonged to more than 30 years age group.

40.9% of bacteriuric patients were primigravidae, 11.36% were first para, 36.3% were second para and 11.36% were of third or more parity.<sup>29</sup>

In 1982, PK Chng and Marion H Hall found that on comparing the relation of ASB to previous history of UTI, 50 (23.6%) of the 212 women who had bacteriuria had a past history which had been compared with 311 (19.7%) of the 1575 women who did not have bacteriuria.<sup>30</sup>

In 1987, P Yashodhara, Rita Mathur and Leela Raman, in their study reported that ASB was found in 7.73 percent of pregnant women belonging to the low socio-economic status group and 10.5 percent of the women belonging to upper income group. In the low income group, 3.88% belonged to 19 years age group, 8.8% to 20-28 years age group and 8.1% to 29 years age group. 4.26% were primigravidae, 8.33% were first para, 10.2% were second para and 8.28% were  $\geq$  third para. 9.68% of bacteriuric patients belonged to  $\leq$  12 weeks gestation, 7.6% to 13-28 weeks and 7.7% to  $>$  29 weeks gestation.

In the higher income group, 17.14% belonged to 19 years age group, 8.96% to 20-28 years age group and 11.1% to 29 years age group. 13.56% were primigravidae, 8.57% were first para and 8.51% were second parae, 5.5% of bacteriuric patient belonged to  $\leq$  12 weeks gestation, 8.57% to 13-

28 weeks and 12.72% of bacteriuric patient belonged to > 29 weeks gestation.<sup>31</sup>

In 1996, G Nath, M Chaudhary, Jai Prakash, et al. in their study found that 5.26% of bacteriuric women belonged to < 25 years age group, 10.36% to 25-29 years group and 12.43% to  $\geq$  30 years age group. Third trimester was associated with highest number of cases (11.9%), followed by second (7.5%) and first (5.7%). Primigravidae had higher number of culture positivity with significant bacteriuria (11.47%) than multiparous women (7.04%). They have also stated that the prevalence of ASB depends among other factors on the socioeconomic status of the population.<sup>32</sup>

In 1997, A.B. Maclean has stated that the incidence had an increase with in age and gravida and that it was higher in patients belonging to low socio-economic groups.<sup>33</sup>

In 1999, Maria C Savoia has stated that incidence of bacteriuria in pregnancy was found to increase with age, sexual activity, parity and socioeconomic status. Also it stated that the prevalence was higher in subgroups who were diabetics, around 12.5% and in those who had a history of prior UTI it was 18.5%.<sup>34</sup>

In 2002, SV Lavanya and D Jogonalakshmi in their study found that the incidence was higher in less than 20 years age groups, i.e. 71.42%,

66.6% of the cases were primigravida, 7.2% were first para, 9.6% were second para and 16.6% were multiparous. Their study also revealed that the incidence increased as socio-economic status of the patients decreased.<sup>35</sup>

In 2003, Deborah A Wing has stated that prevalence of ASB in pregnancy is 2-10% and is influenced by socioeconomic status, parity, age, sexual practice, diabetes mellitus and sickle cell anaemia.<sup>36</sup>

### **NORMAL FLORA OF THE GENITOURINARY TRACT:<sup>37</sup>**

*Mycobacterium smegmatis*, a harmless commensal, is found in the smegma of the genitalia of both men and women. This may cause confusion by its presence in the voided specimens of urine. The female urethra is generally sterile. Sometimes the female urethra contains a few Gram positive cocci.

The vulva of the newborn child is sterile but after 24 hours it acquired a varied flora of nonpathogenic organisms from the skin, vagina and intestines. The nature of the flora in the vagina depends on the pH of its secretions and its enzyme content.

In the first 24 hours it is invaded by micrococci, enterococci and diphtheroids. In 2-3 days, the maternal estrin induces glycogen deposition

in the vaginal epithelium. This facilitates the growth of a lactobacillus namely Doderlien's bacillus which produces acid from glycogen, and the flora for a few weeks is similar to that of the adult. After the passively transferred estrin has been eliminated in the urine, the glycogen disappears, along with Doderlien's bacillus and the pH of the vagina becomes alkaline. This brings about a change in the flora to micrococci, alpha and non hemolytic streptococci, coliforms and diphtheroids.

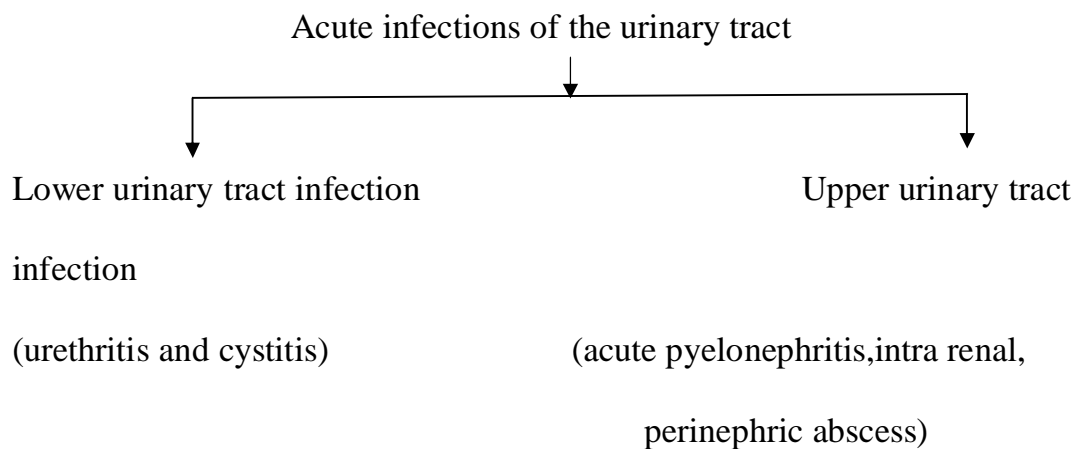
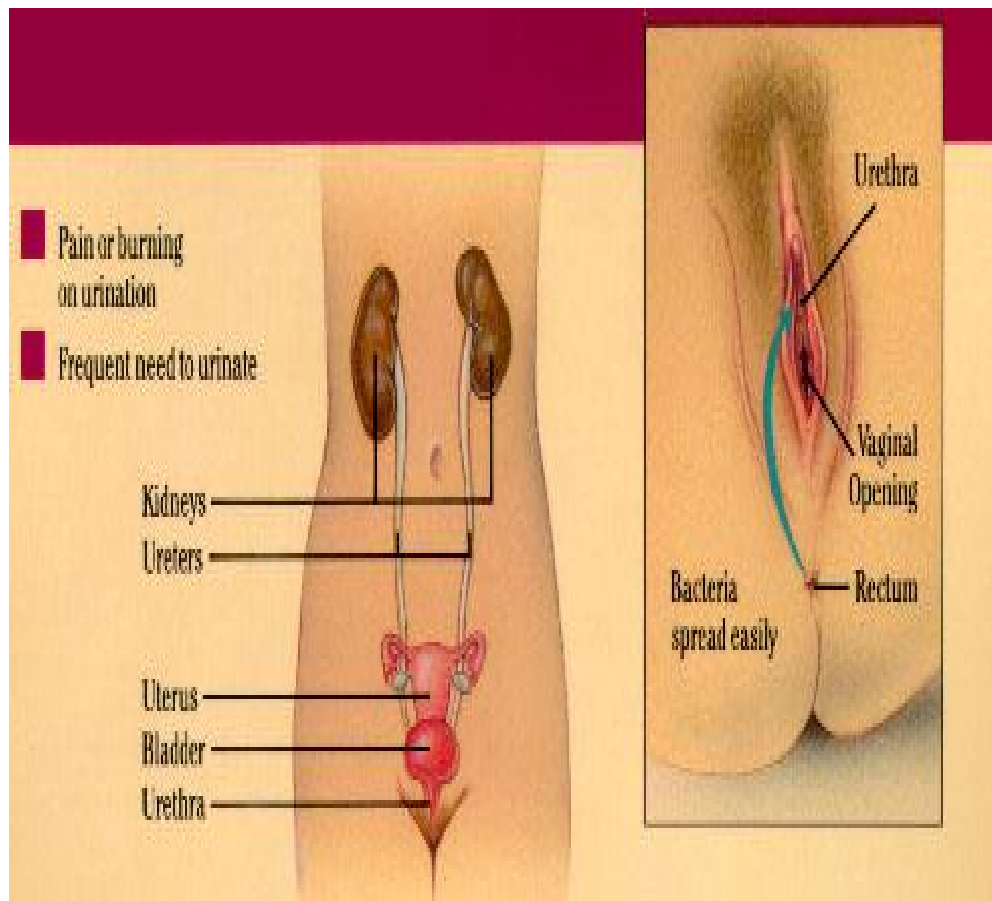
At puberty, the glycogen reappears and the pH changes to acid due to the metabolic activity of Doderlien's bacilli, E.Coli and yeasts. This change probably helps in the prevention of colonization by possible harmful micro organisms.

During pregnancy there is an increase in Staphylococcus epidermidis, Doderlien's bacilli and yeasts. Occasionally other members of the intestinal flora may be present.

After menopause, the flora resembles that found before puberty.

The normal vaginal flora often includes anaerobic cocci and bacilli, listeria, anaerobic streptococci, mimeae, mycoplasma, Gardnerella vaginalis, neisseriae and spirochetes.

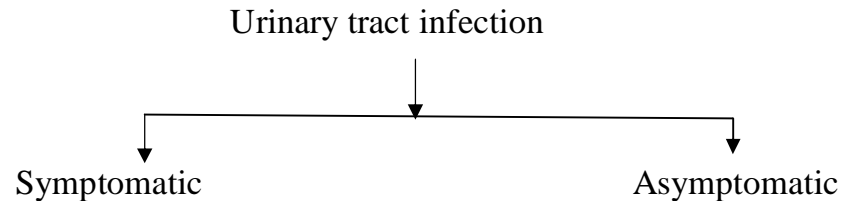
## URINARY TRACT INFECTIONS:<sup>38</sup>



Infections of the urethra and bladder are often considered superficial or mucosal infections, whereas pyelonephritis and renal suppuration are considered to be tissue invasion.



Urinary tract infection is said to be present pathogenic micro organisms are found to be detected in the urine or in the urinary tract- kidney, urethra or bladder.



In most cases, the presence of  $> 10^5$  organisms/ milliliter in a mid stream “clean catch” sample of urine indicates infection of the urinary tract. So the presence of  $>10^5$  micro organisms in a urine sample is called significant bacteriuria.

Symptoms accompanied by significant bacteriuria is symptomatic urinary tract infection.

Only significant bacteriuria without any symptoms is asymptomatic urinary tract infection.

Symptoms such as dysuria, urgency of micturition, frequency of micturition, lower abdominal pain and sometimes fever that are not associated with significant bacteriuria has been given the term “acute urethral syndrome”.

Pyelonephritis denotes bacterial infection of the kidney. This is believed to result from interstitial nephritis. Sometimes non infectious causes may result in a similar picture as of chronic pyelonephritis which is indistinguishable pathologically from chronic pyelonephritis.

### **MICROBIOLOGY:**<sup>38</sup>

The aetiologic agents associated with Bacteriuria in pregnancy as well as in non-pregnant state is caused by similar causative organisms. The length of the urethra in female is relatively lesser. This predisposes to frequent colonization with organisms that colonize the gastro intestinal tract.

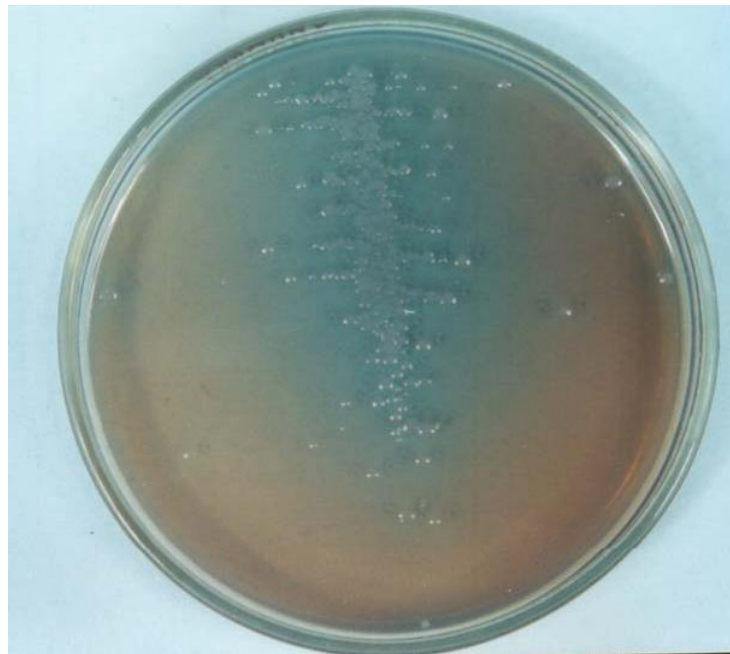
Bacteriuria with symptoms and also without symptoms is most commonly caused by *E. coli*. The association of *E.Coli* is regarded significant. This represents about 70% to 80% of isolated micro organisms.

CLED medium showing pink semi translucent colonies of *E.Coli*



Proteus, Klebsiella and rarely enterobacter species which are gram negative organisms form the cause of a minority of urinary tract infection which is not complicated. Much importance is attributed to all the above mentioned organisms including Serratia species and Pseudomonas species in playing a role in repeated infections of urinary tract and also in urinary tract infections in association with renal stones, any block in the urinary tract and urological manipulations.

CLED medium showing blue green semitranslucent colonies of *Proteus mirabilis*



Urinary tract infections are less commonly caused by Gram positive cocci. But, younger female patients, 10-15% of urinary tract infections which present acutely is caused by *Staphylococcus saprophyticus* species.

Enterococcus and Staphylococcus aureus play an important role in causing infections in women with renal stones and in those with previous instrumentation and previous surgeries. Staphylococcus epidermidis is mostly associated with catheter associated urinary tract infection.

In women who have acute urinary symptoms, who present with pyuria, but sterile urine even in suprapubic aspiration collection of urine usually demonstrate organisms which are sexually transmitted urethritis producing agents like Chlamydia trachomatis as well as Neisseria gonorrhoeae and herpes simplex virus.

Other unusual bacteria which have been isolated from pregnant women having symptoms of urinary tract infection or not, are Ureaplasma urealyticum as well as Mycoplasma hominis.

Among viral infections, adenoviruses cause acute haemorrhagic cystitis in children and also in some young adults. Candida and other fungal species have been isolated from urine specimens of catheterized or diabetic patients. These may sometimes progress to symptomatic invasive infection.

## **PATHOGENESIS OF URINARY TRACT INFECTION:**<sup>38,23</sup>

Urinary tract is regarded as a continuous tract containing a column of urine extending from urethra to the kidney. Urethra is the entry point for all infections of the urinary tract. Pyelonephritis of the kidney is caused by these infections which ascend from the bladder which had already gained entry through the urethra.

In females the gram negative organisms which reside in the bowel colonize the vaginal introitus, periurethral skin and the lower urethra. So females are prone for cystitis.

The factors favouring peri urethral colonization in females are :

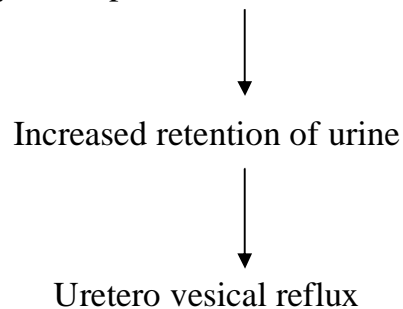
- 1.Alteration of normal bacterial flora of vagina by antibiotics
- 2.Genital infections
- 3.Contraceptives
- 4.Loss of H<sub>2</sub>O<sub>2</sub> producing lactobacilli which is normally dominant
- 5.Urethral massage during intercourse

More so pregnancy itself pose increasing risk for urinary tract infection. The risk is increased in pregnant women from 6 weeks to 24 weeks of gestational period because almost in each one of antenatal

women, the ureter is dilated and this dilatation is the same till labour. This is being referred by the term-“hydronephrosis of pregnancy”.

Factors predisposing to upper tract infection in pregnancy :

- Bladder volume is increased
- Bladder tone is decreased
- Ureteral tone is decreased
- Ureteral peristalsis is decreased
- Temporary incompetence of the vesicoureteral valve



Added to this, there is functional rise in volume of plasma in pregnant women. This reduces concentrating ability and thus resulting in diluted urine. Furthermore in 70% of pregnant women develop glycosuria, where glucose in urine favours growth of bacteria in urine.

There is a reduced resistance of the urinary bladder and urethra in pregnant women to the invasion of micro organism due to increased

progesterone getting excreted in urine as well as due to estrogens. This reduced capacity is also due to decreased ureteral tone and may also be allow certain species of bacteria to grow in a selective fashion. Thus the above mentioned factors favour the development of urinary tract infections during pregnancy.

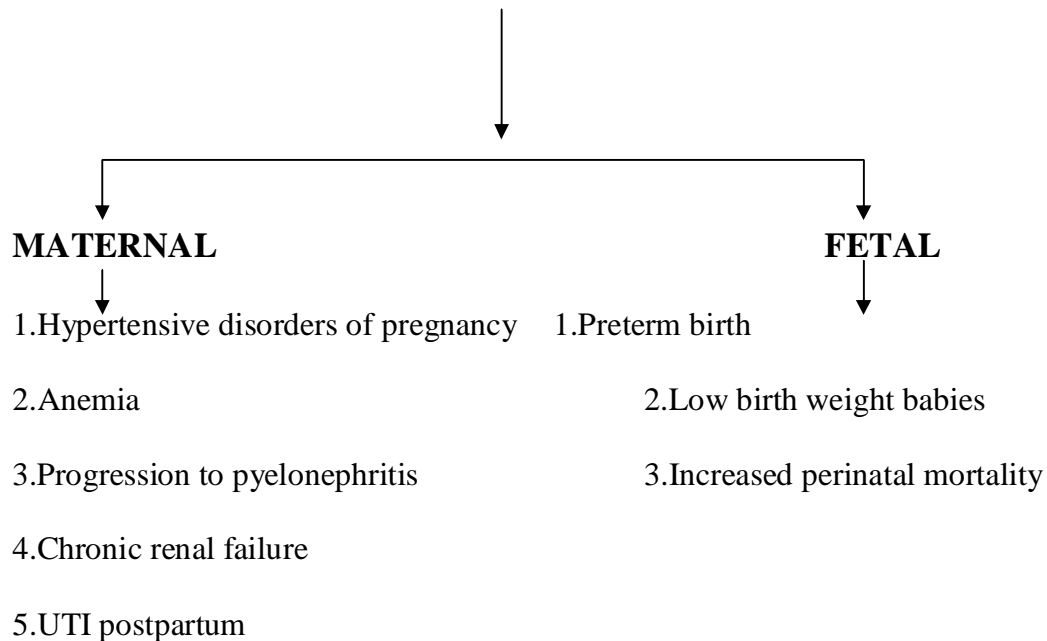
### **COMPLICATIONS ASSOCIATED WITH ASYMPTOMATIC BACTERIURIA OF PREGNANCY**

It is well established that ASB has serious outcomes in pregnancy. Pregnant women with asymptomatic bacteriuria have an increased risk of pyelonephritis and there is a strong association between ASB and preterm and low birth weight delivery.

Other complications of pregnancy associated with bacteriuria such as anaemia, hypertension or long-term renal function impairment have also been documented.

## COMPLICATONS ASSOCIATED WITH ASYMPTOMATIC

### BACTERURIA



In 1960, Kass has shown that 40 percent of patients with bacteriuria develop overt urinary tract infection.<sup>39</sup>

### *Acute pyelonephritis*

Acute pyelonephritis can be described as the acute bacterial infection of the kidney presenting with fever, and mostly flank pain.

When concentrated, 20-40% of mothers with ASB will develop acute pyelonephritis.

Non-pregnant women with ASB rarely develop pyelonephritis. Acute bacterial pyelonephritis is frequent in pregnant women and occurs in



1-4% of all pregnant women (Kass, 1973). Of the women who develop pyelonephritis during pregnancies, 60-75% acquires it during the third trimester. Women with persistent bacteriuria may have increased incidence of impaired creatinine clearance and urinary concentrating ability.

The mechanisms of the impairment may be due to direct involvement of the renal concentrating mechanisms by infection, an increase in the hydronephrosis of pregnancy due to infection and malfunction of the ureters and changes in the concentrating mechanism secondary to slight reductions in the GFR.

The marked dilatation of the ureters during the later stages apparently allows bacteria in the bladder to reach the upper tract and to produce symptomatic pyelonephritis. Over 75% of the cases of acute pyelonephritis can be prevented by eliminating asymptomatic bacteriuria in the early stages of pregnancy. Kass in 1959 reported that there was an association between ASB and prematurity and that the eradication of bacteriuria significantly reduced the rate of premature delivery.

In a study at WHMC, it was found that the annual incidence of acute pyelonephritis decreased from 4% to 0.8% and this decrease correlated with the eradication of ASB.

A sharp reduction in the annual incidence of pyelonephritis (1.8% to 0.6%) occurred in an another study after the introduction of a program to screen and treat ASB among pregnant women.

As early as in 1976, Eschenbach has stated that acute pyelonephritis is an important and serious complication of pregnancy which usually develops in women with ASB.<sup>40</sup>

### ***Preterm labour and low-birth weight***

Antepartum urinary tract infection has also been implicated as a risk factor for adverse perinatal outcomes like premature birth with and/or LBW and perinatal death.

In the pre-antibiotic era itself, it was well documented that pyelonephritis of pregnancy was associated with preterm delivery was well known. The rate of pre maturity can be as high as 20-50%. In general, it seems that pre maturity and LBW are increased in patients refractory to multiple courses of therapy. They have been reported to have a significantly LBW infants than in those who responded.

In a meta-analysis it was proven that if ASB in pregnancy was not treated, it resulted in higher rates of LBW and preterm delivery.

The mechanism by which ASB promotes preterm labour is not clear, but subclinical amnionitis or phospholipids A2 production by bacteria have been proposed.

In another study, LBW newborns and small for gestational age newborns were respectively 2.04 and 1.57 times more frequent in UTI associated pregnancies compared to controls.

Incidence of prematurity was 75% and that of LBW was 50% in untreated patients of ASB in a study in India.

In 1992, Robert Mittendorf, Michelle A Williams and Edward H Kass have reported from their meta analytical study that bacteriuric mothers were found to have a 54% higher risk of giving birth to LBW infants and twice the risk of giving birth to a preterm infant than non bacteriuric mothers.<sup>27</sup>

Associations have been documented between antepartum UTI and variety of maternal complications of pregnancy, including hypertension/preeclampsia, anaemia, amnionitis and endometritis, long-term renal function impairment..

In 1994, Schieve and colleagues, in their study reported increased risks for low birthweight, preterm delivery, hypertension or preeclampsia and maternal anaemia.<sup>41</sup>

In 2001, Larry C Gilstrap III and Susan M Ramin have stated that failure to treat bacteriuria during pregnancy may result in as many as 25% of women experiencing acute pyelonephritis and women having acute pyelonephritis might end up in certain consequences, like premature delivery, renal failure, Acute Respiratory Distress Syndrome, sepsis, shock, and haematologic abnormalities.<sup>42</sup>

In 2002, Richard L Sweet and Ronald S Gibbs have stated that untreated ASB during pregnancy often leads to acute pyelonephritis in 20% to 30% of cases.<sup>4</sup>

There is an association between maternal UTI and foetal death and mental retardation or developmental delay. Glial cells are either destroyed or transformed by endotoxin can lead to perinatal leukoencephalopathy and death. The probability of women with untreated UTI having a child with mental retardation or developmental delay was 35% higher than the unexposed group.

## **DIAGNOSIS:**

In 1941, Marple pointed out that colony counts were imperative in order to differentiate contamination from significant bacteriuria and introduced the pour-plate technique for the quantitative culture.<sup>3</sup>

### **Pour – plate method**



In 1962, Simmons and Williams introduced TTC (Triphenyl Tetrazolium Chloride) test.<sup>43</sup>

## **Triphenyl Tetrazolium Chloride test**



The semi quantitative bacteriological procedures most widely used were the standard loop technique of Guttman and Stokes (1963) and the filter paper strip method of Leigh and Williams (1964).<sup>44</sup>

## **Standard loop method**

### **E.coli colonies on blood agar**



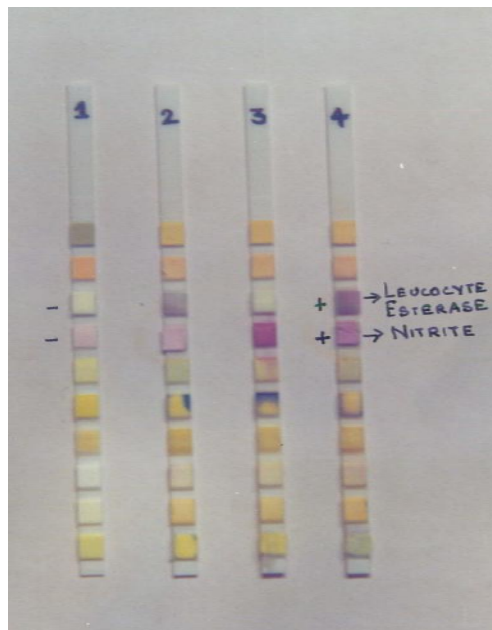
## Standard loop method

### E.Coli colonies on MacConkey agar



In 1989, Flangan et al. recommended screening by dipstick tests for nitrite and leukocyte esterase.<sup>45</sup>

### Dipstick tests for nitrite and leukocyte esterase



In 1990, Michael D.D. McNeely stated that urine analysis was the oldest of all clinical laboratory examination.<sup>46</sup>

In 1996, Zion Hagay, Roni Levy, Avraham Miskin et al. stated that Uriscreeen test (Catalase test) was a reliable alternative to culture screening of all pregnant patients.<sup>47</sup>

### **Catalase test**



In 1998, Betty A Forbes, Daniel F Sahm, Alice S Weissfeld stated that many screening methods have been advocated for use in detecting bacteriuria and/or pyuria, and these include microscopic methods, colorimetric filtration, bioluminescence, electrical impedance, enzymatic methods, photometric detection of growth and enzyme immune assay, automated and semiautomated systems.



Acute urinary tract infection is first diagnosed by clinical signs and symptoms with which it presents.

The criteria commonly used to make the diagnosis of asymptomatic bacteriuria is the growth in solid culture of 100000 or more colonies( $>10^5$  colony-forming units or CFU)by a single midstream catch technique.

Some women have lower colony counts that probably reflect the efficacy of the bladder washout and bacteriuria should be suspected if the colony count is between  $20^5$  and  $100^5$ /ml. In these cases the urine analysis may be useful and if there are more than 10 leukocytes/ml or the dipstick reveals leukocyte esterase or nitrates, most likely the the patient has asymptomatic bacteriuria with a low colony count. A CFU of  $20^5$ /ml is also diagnostic if the urine sample is obtained by catheterization.

Screening for asymptomatic bacteriuria should occur at the first prenatal visit(Nicolle et al.,2005). The screening is done by culture of a urine specimen obtained by mid stream catch.A urine dipstick is not an adequate substitute for urine culture and has unacceptably high false positive and false negative results. A positive nitrate test is only given by enterobacteria that convert nitrate to nitrite and leucocyte esterase is positive only when significant pyuria is present.<sup>48</sup>

Unfortunately, screening only once early in gestation will not detect more than one-third of the women who will develop pyelonephritis. The detection rate increases with a second and even more with a third screening during pregnancy, but this is only justified in women at high risk for some of the complications associated with bacteriuria, such as preterm labor.

### **SPECIMEN COLLECTION:**

As of date, no recommended method has been reported for collecting urine as a specimen. Standard technique that is approved is to first clean the perineum and urethra and then mid stream urine voided in clean conditions is collected. But there are not enough evidence to support that this technique will reduce contamination and moreover it is not cost-effective.

Urine specimen can be collected by the following methods:<sup>49</sup>

- Mid stream urine
- Catheter collection
- Suprapubic aspiration

### **MID STREAM URINE:**

Urine samples are usually collected by the clean catch technique by obtaining the mid stream flow. First the periurethral area and the perineum

are cleansed with two to three washes with clear water, in a forward to backward motion. The labia should be held apart, if possible, during voiding. The first few milliliters of urine passed are discarded to flush out bacteria contaminating the urethra. This clean catch mid stream sample of urine is then collected in a wide mouthed sterile container that could be covered with a tightly fitted lid.

### **CATHETER COLLECTION:**

Catheterization should best be avoided for obtaining urine sample as by catheterization for the purpose of screening asymptomatic bacteriuria, by itself, has a high risk of introducing nosocomial infection. Thus this method for collection of urine should be restricted only to those patients who are unable to void a midstream sample. However, it should be performed only with meticulous attention to aseptic technique.

### **SUPRAPUBIC ASPIRATION:**

Though it is a cumbersome procedure, suprapubic aspiration is a method by which the urine is obtained by the most sterile technique. Here the urine is withdrawn directly by a sterile syringe through a needle which is inserted percutaneously, after cleansing the area with sterile pad soaked in soapy water. This ensures collection of a contamination free sample.

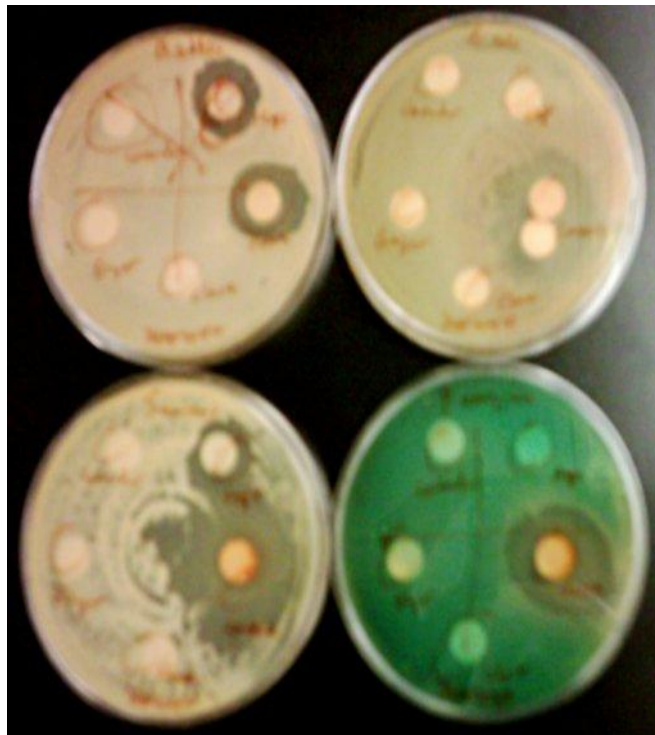
## **SPECIMEN TRANSPORT:**

Since urine is an excellent supportive medium for the growth of most bacteria, when the sample is to be transported, the urine sample must be immediately refrigerated or preserved. Bacterial counts will remain constant in refrigerated urine for as long as 24 hours.<sup>49</sup>

## **TREATMENT:**

Asymptomatic bacteriuria should be treated with antibiotics which have been found to be sensitive to the micro organism isolated. The antibiotic sensitivity has been detected by antibiotic susceptibility test (Kirby Bauer's disc diffusion method).

**Antibiotic susceptibility test (Kirby Bauer's disc diffusion method).**



### Drugs which act against specific organisms

	<b>Drug</b>	<b>Organisms sensitive</b>
1	Amoxicillin	Some E. coli, most Proteus spp., Group B Streptococci, Enterococcus spp., some Staphylococci spp.
2	Amoxicillin – Clavulanic acid (Augmentin)	Most gram negative aerobic bacilli and gram positive cocci
3	Ampicillin	Some E. coli, most Proteus species, group B Streptococcus, Enterococcus spp., some Staphylococci spp.
4	Cephalexin	Most E. coli, most Klebsiella and Proteus species, group B Streptococci, Staphylococci spp.
5	Nitrofurantoin monohydrate macrocrystals – sustained release preparation	Most gram negative aerobic bacilli
6	Sulfisoxazole	Most gram negative aerobic bacilli
7	Trimethoprim-Sulfamethoxazole double strength	Most gram negative aerobic bacilli

Once bacteriuria is identified, antenatal women should be promptly treated. But certain antibiotics have a deleterious effects on the fetus. So their use is precluded for treating bacteriuria. These drugs are :

1. Tetracyclines - discolouration of fetal teeth and bony defects, congenital defects
2. Quinolones - congenital deformities
3. Trimethoprim, early in pregnancy -facial dysmorphisms, heart defects)
4. Chloramphenicol and sulfonamides, late in pregnancy - Gray syndrome.<sup>50</sup>

<b>Antibiotics</b>	<b>Dosage</b>	<b>Drug Category in pregnancy</b>
Cephalexin	250 mg bd/qid	B
Erythromycin	250-500 mg qid	B
Nitrofurantoin	50- 100 mg qid	B
Sulfisoxazole	1g qid	C
Amoxicillin-clavulinic acid	250 mg qid	B
Fosfomycin	One 3g sachet	B
Trimethoprim-Sulfamethoxazole	160/180 mg bd	C

From the beginning, the drug of choice had been ampicillin, but recently, E.Coli has been showing increased resistance to ampicillin.<sup>11,12</sup> Nitrofurantoin is a good choice because of its high concentration in urine. Treatment for 10 days with 100 mg nitrofurantoin at bedtime is usually effective. Alternatively cephalosporins can also be used.

An antibiotic given for 7 to 10 days for treating asymptomatic bacteriuria is generally enough to eradicate the causative organisms, although shorter courses have been described with conflicting results.

One of the most commonly used is nitrofurantoin, 100 mg orally twice daily for 3-7 days. Trimethoprim-sulfamethoxazole (one tablet orally twice a day, single or double strength for 3 days), amoxicillin (500 mg orally three times a day for 3-7 days), amoxicillin-clavulanate (500 mg orally twice daily for 3-7 days), and cephalexin (500 mg orally twice daily for 3-7 days) can be used with similar success. However, resistance to amoxicillin and sulfonamides is common and it is better to select a drug after determining the antibiotic sensitivity of the bacteria.

Masterton showed a cure rate of 88% using a single dose of ampicillin, 3 g in isolates which were ampicillin- sensitive. Many other studies reported that a single dose regimen using amoxicillin, cephalexin or nitrofurantoin was found to have a lesser success rate of 50 – 78% to eradicate bacteriuria in pregnancy. Fosfomycin which is available as 3 g sachet is found to be effective as a single dose.<sup>50</sup>

The success of treatment should be affirmed by a repeat culture of urine one week after finishing treatment and the sterility of urine confirmed by monthly cultures during the pregnancy. The recurrent rate for

all the regimens is about 30%. Their failure to eradicate bacteriuria may indicate underlying upper UTI and need for longer therapy. Nitrofurantoin 100 mg daily for 21 days has been found to be effective for treatment failures. For women with bacterial persistence or recurrence, suppressive therapy for remainder of the pregnancy with nitrofurantoin 100 mg daily may be advised. Continuous daily treatment is also necessary for patients who have relapses following successful treatments or who are reinfected by a different bacterial species.

Villar et al conducted the The Cochrane Review to compare the efficacies of various durations for treating asymptomatic bacteriuria. Finally he came to a conclusion that enough evidence was not available to prove if a single-dose and multi-doses were the same in the treatment of asymptomatic bacteriuria.

The relative risk was calculated to assess if the treatment failure for asymptomatic bacteriuria was more for single dose treatment compared to multi dose treatment (RR 1.25, 95% CI 0.93, 1.67). But even then there was no statistical difference. Single-dose treatment showed reduced incidence of adverse-effects, however (RR 0.52, 95% CI 0.32,0.85).

Current recommendation is that conventional treatment regimens should be utilized for treating asymptomatic bacteriuria during pregnancy (Cochrane review).



**Oral Antimicrobial Agents used for treatment of pregnant women  
with Asymptomatic Bacteriuria<sup>51</sup>**

**Single- dose treatment**

Amoxycillin 3 g

Ampicillin 2 g

Cephalosporin 2 g

Nitrofurantoin 200 mg

Trimethoprim-sulfamethoxazole 320/1600 mg

**3-day course**

Amoxicillin 500 mg three times daily

Ampicillin 250 mg four times daily

Cephalosporin 250 mg four times daily

Ciprofloxacin 250 mg twice daily

Levofloxacin 250 mg daily

Nitrofurantoin 50 to 100 mg four times daily; 100 mg twice daily

Trimethoprim-sulfamethoxazole 160/800 mg two times daily

**Other**

Nitrofurantoin 100 mg four times daily for 10 days

Nitrofurantoin 100 mg twice daily for 7days

Nitrofurantoin 100 mg at bedtime for 10 days

**Treatment failures**

Nitrofurantoin 100 mg four times daily for 21 days

**Suppression for bacterial persistence or recurrence**

Nitrofurantoin 100 mg at bedtime for remaining period of pregnancy

## **AIMS OF THE STUDY**

- To study the prevalence of asymptomatic bacteriuria in antenatal women attending antenatal clinic in Government Kilpauk Medical College Hospital.
- To study the association of the following risk factors in asymptomatic bacteriuria
  1. Age
  2. Gravida
  3. Socio economic status
  4. Trimester
  5. Past H/O UTI
- To compare the effectiveness of the single dose antibacterial treatment with multidose treatment for asymptomatic bacteriuria during pregnancy

## MATERIALS AND METHODS

- ▶ Ethical committee clearance obtained in February 2011
- ▶ Study design - prospective randomized controlled trial
- ▶ Place of study - Antenatal op in KMCH
- ▶ Duration of study - June 2011 to September 2012
- ▶ Sample size – 310 calculated by the formula

$$n = z^2_{1-\alpha/2} P (1-P) / d^2$$

n-sample size

z-table value (1.96)

P-prevalence

d-constant (0.05)

- ▶ 310 women with asymptomatic bacteriuria is divided equally into 155 for both treatment groups.

### INCLUSION CRITERIA:

- 1) All antenatal women irrespective of gestational age without any symptoms of urinary tract infection.

### **EXCLUSION CRITERIA:**

- 1) Antenatal women with symptoms of UTI.
- 2) Antenatal women who were and are on antibiotics for any cause .
- 3) Presence of renal abnormalities.
- 4) Presence of renal calculi.

### **METHOD OF COLLECTION OF DATA**

All antenatal women attending antenatal clinic in Government Kilpauk Medical College Hospital for a routine check up and those who all fall in the inclusion criteria will be asked to collect a sample of clean catch, midstream urine in sterile wide mouthed containers with lid.

The sample is sent for culture and sensitivity to the laboratory.

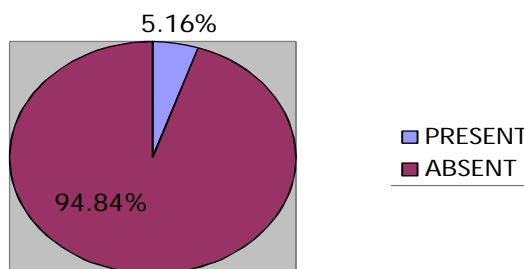
Standard procedures are used to identify the micro organism grown in the culture in significant number. Then the sensitive antibiotic is obtained by subjecting them to antibiotic susceptibility test (Kirby Bauer's disc diffusion method). After detection of asymptomatic bacteriuria, a course of antibiotic treatment is given. Follow up is done and after 7 days of completing the treatment a repeat urine culture is done to know the response to the treatment.

## ANALYSIS AND RESULTS

### PREVALENCE OF ASYMPTOMATIC BACTERIURIA IN PREGNANT WOMEN

In a study population of 6000 antenatal women attending antenatal clinic, the prevalence of asymptomatic bacteriuria in pregnant women was found to be 310/6000, that is 5.16% which correlates with the normal incidence of 2-10% of asymptomatic bacteriuria in pregnancy.

#### ASYMPTOMATIC BACTERIURIA IN PREGNANT WOMEN

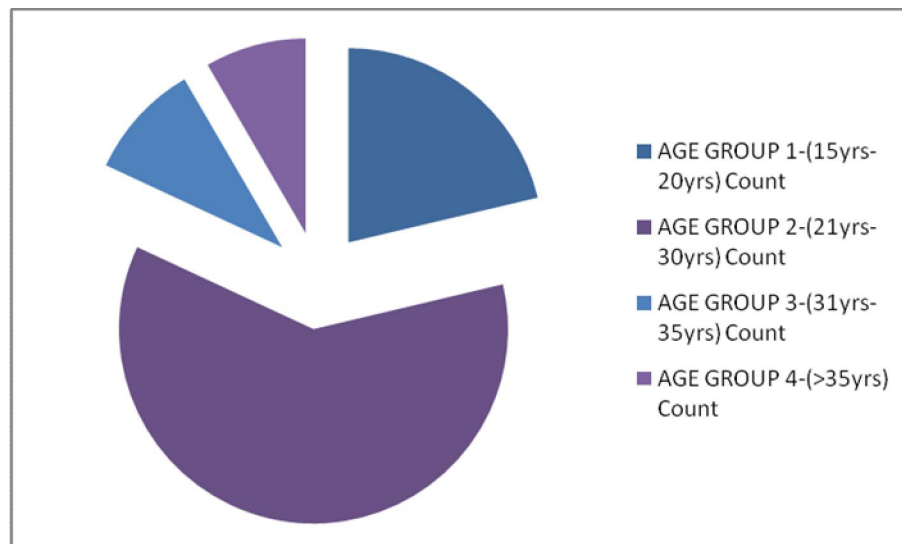


## **PREVALENCE OF ASYMPTOMATIC BACTERIURIA ACCORDING TO AGE WISE DISTRIBUTION**

1-(15yrs-20yrs)-67  
2-(21yrs-30yrs)-180  
3-(31yrs-35yrs)-38  
4-(>35yrs)-25

From the above data, it was found that 21.61% were in the age group 15-20 yrs, 58.06% were in the age group 21-30 yrs, 12.25% were in the age group 31-35 yrs and 8.06% were in the age group >35yrs.

### **AGE DISTRIBUTION**



**PREVALENCE OF ASYMPTOMATIC BACTERIURIA  
ACCORDING TO AGE WISE DISTRIBUTION**

			DOSE		
			1-single dose	2-multi dose	Total
AGE GROUP	1-(15yrs-20yrs)	Count	33	34	67
		% within DOSE	21.3%	21.9%	21.6%
		% of Total	10.6%	11.0%	21.6%
	2-(21yrs-30yrs)	Count	94	86	180
		% within DOSE	60.6%	55.5%	58.1%
		% of Total	30.3%	27.7%	58.1%
	3-(31yrs-35yrs)	Count	15	23	38
		% within DOSE	9.7%	14.8%	12.3%
		% of Total	4.8%	7.4%	12.3%
	4-(>35yrs)	Count	13	12	25
		% within DOSE	8.4%	7.7%	8.1%
		% of Total	4.2%	3.9%	8.1%

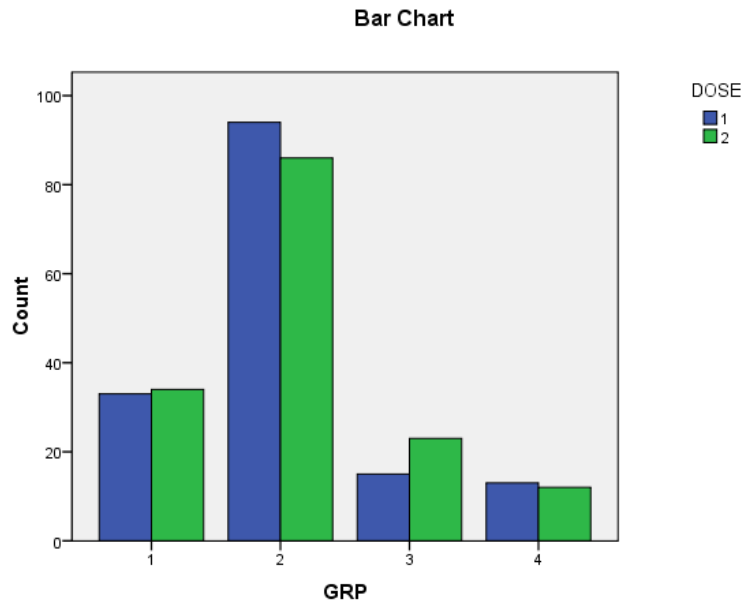
This table shows that women with asymptomatic bacteriuria, more commonly fall in the age group – 21- 30 yrs and constitute around 58.1%.

According to Pearson Chi-Square test, p value is 0.553

Age is considered to play an important role as a risk factor for asymptomatic bacteriuria.



## PREVALENCE OF ASYMPTOMATIC BACTERIURIA ACCORDING TO AGE WISE DISTRIBUTION



1-(15yrs-20yrs)

2-(21yrs-30yrs)

3-(31yrs-35yrs)

4-(>35yrs)

This graph shows that asymptomatic bacteriuria is more common in the age group – 21- 30 yrs.

### Independent Samples Test

	Levene's Test for Equality of Variances		t-test for Equality of Means		
	F	Sig.	t	Df	Sig. (2-tailed)
AGE Equal variances assumed	.200	.655	-.211	308	.833
Equal variances not assumed			-.211	307.575	.833

### Independent Samples Test

	t-test for Equality of Means			
			95% Confidence Interval of the Difference	
	Mean Difference	Std. Error Difference	Lower	Upper
AGE Equal variances assumed	-.129	.612	-1.332	1.074
Equal variances not assumed	-.129	.612	-1.332	1.074

## PREVALENCE OF ASYMPTOMATIC BACTERIURIA-SOCIO ECONOMIC STATUS WISE DISTRIBUTION

No of women in socio economic classV - 190

IV - 118

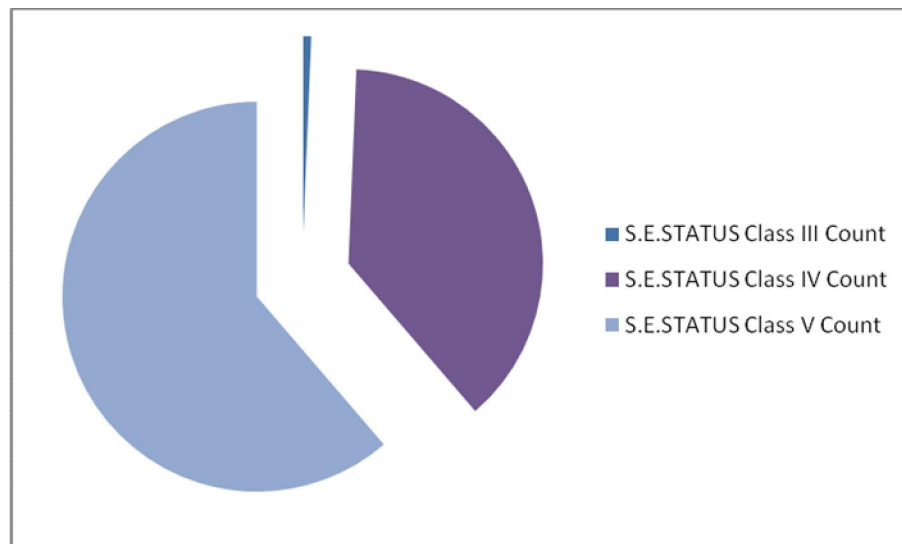
III - 2

II - 0

I - 0

From the above data it was found that 61.29% of women in socioeconomic class V, 38.06% of women in socioeconomic class IV and 0.64% of women in socioeconomic class III had asymptomatic bacteriuria. This shows that asymptomatic bacteriuria is more prevalent in low socioeconomic status.

### SOCIOECONOMIC CLASS



**PREVALENCE OF ASYMPTOMATIC BACTERIURIA-SOCIO  
ECONOMIC STATUS WISE DISTRIBUTION**

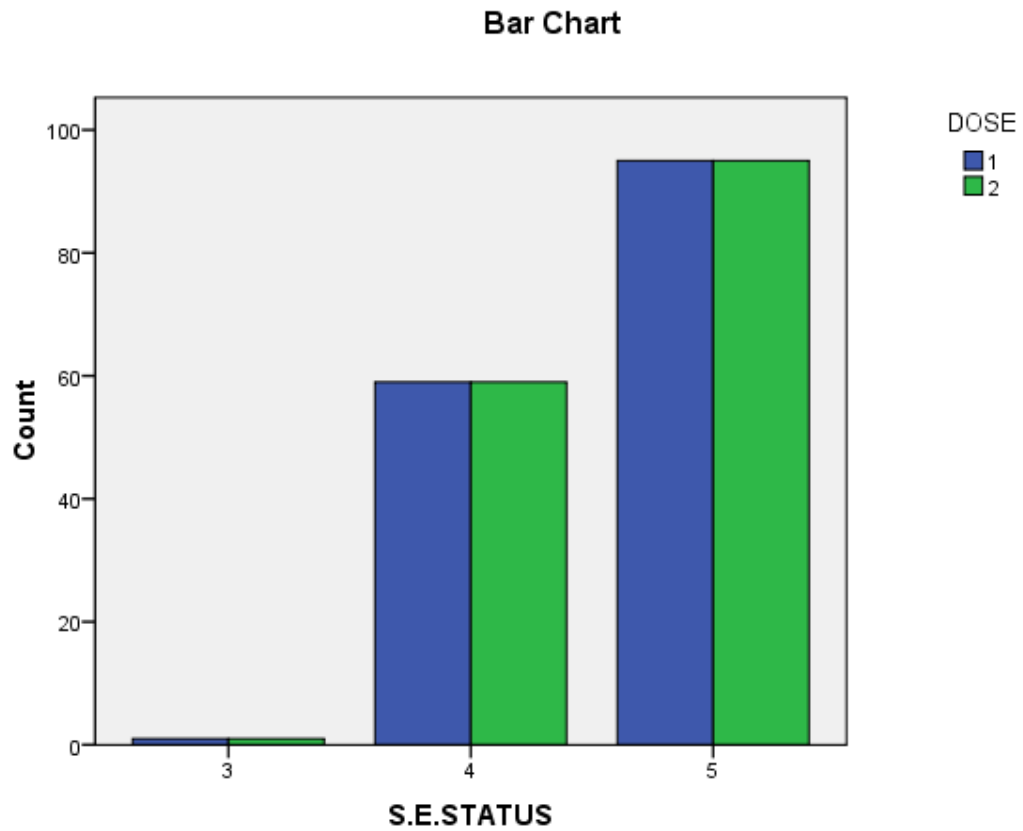
			DOSE		Total
			1-single dose	2-multi dose	
S.E.STATUS	Class III	Count	1	1	2
		% within DOSE	.6%	.6%	.6%
		% of Total	.3%	.3%	.6%
	Class IV	Count	59	59	118
		% within DOSE	38.1%	38.1%	38.1%
		% of Total	19.0%	19.0%	38.1%
	Class V	Count	95	95	190
		% within DOSE	61.3%	61.3%	61.3%
		% of Total	30.6%	30.6%	61.3%

It is demonstrated that 61.3% of women, who have been found to have asymptomatic bacteriuria are from socio economic class V.

According to Pearson Chi-Square test, p value is 1.0

Lower socioeconomic status is a definite risk factor for asymptomatic bacteriuria

## PREVALENCE OF ASYMPTOMATIC BACTERIURIA-SOCIO ECONOMIC STATUS WISE DISTRIBUTION



3 - Socioeconomic class III

4 - Socioeconomic class IV

5 - Socioeconomic class V

It is clearly shown that asymptomatic bacteriuria is more common in low socioeconomic class.

## **PREVALENCE OF ASYMPTOMATIC BACTERIURIA- GRAVIDA WISE DISTRIBUTION**

No of women who are Primigravida - 183

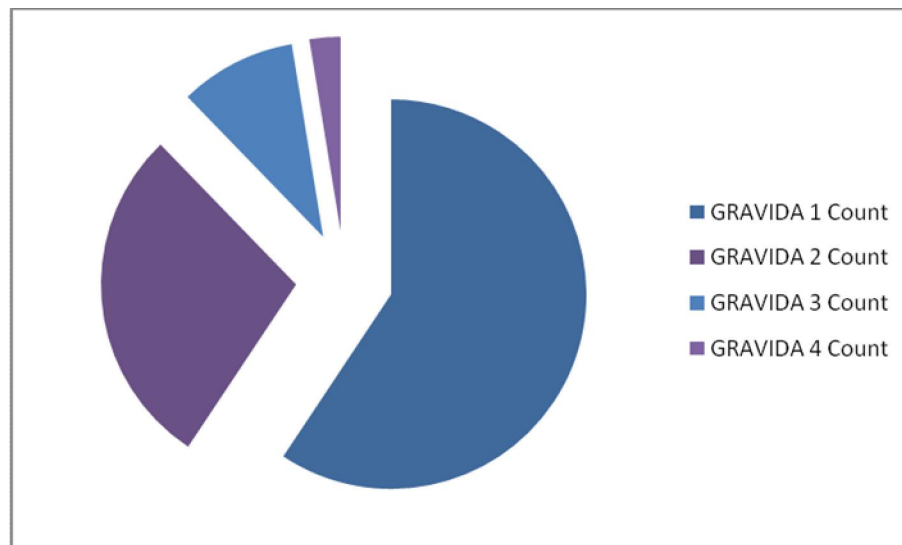
Second gravida - 87

Third gravida - 35

Fourth gravida-5

Out of 310 antenatal women studied, 183 (59.03%) were found to be primigravida, 87 (28.06%) were found to be second gravida, 35 (11.29%) were found to be third gravida and 5 (1.61%) were found to be fourth gravida.

### **GRAVIDA WISE DISTRIBUTION**



# PREVALENCE OF ASYMPTOMATIC BACTERIURIA- GRAVIDA WISE DISTRIBUTION

			DOSE		
			1-single dose	2-multi dose	Total
GRAVIDA	1	Count	92	91	183
		% within DOSE	59.4%	58.7%	59.0%
		% of Total	29.7%	29.4%	59.0%
	2	Count	44	43	87
		% within DOSE	28.4%	27.7%	28.1%
		% of Total	14.2%	13.9%	28.1%
	3	Count	15	20	35
		% within DOSE	9.7%	12.9%	11.3%
		% of Total	4.8%	6.5%	11.3%
	4	Count	4	1	5
		% within DOSE	2.6%	.6%	1.6%
		% of Total	1.3%	.3%	1.6%

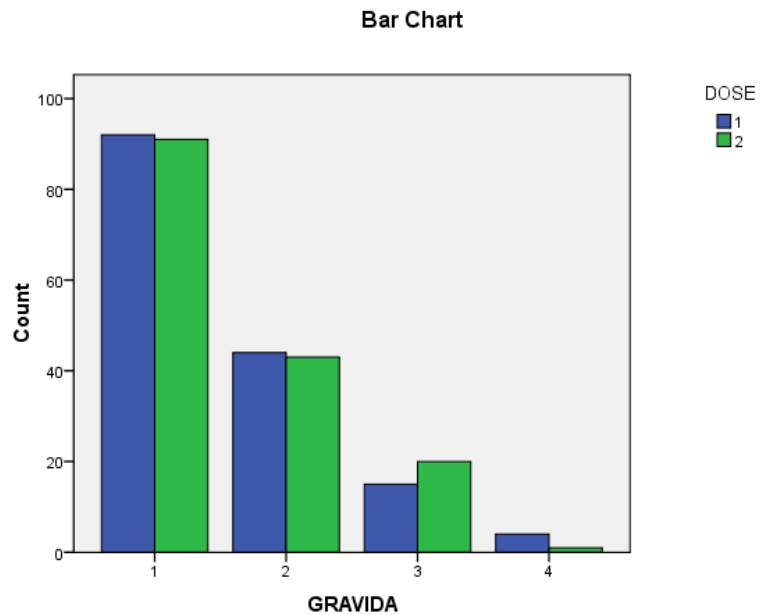
Primigravidas are more prone for urinary tract infection is decipherd from the table well.

According to Pearson Chi-Square test, P value is 0.470.

Highest number is found to be in primi gravida implying that asymptomatic bacteriuria is more common in primi gravida.

Primigravida is considered to be a risk factor for asymptomatic bacteriuria

## PREVALENCE OF ASYMPTOMATIC BACTERIURIA- GRAVIDA WISE DISTRIBUTION



Primigravida - 1

Second gravida - 2

Third gravida - 3

Fourth gravida – 4

Asymptomatic bacteriuria is most common in primigravida.



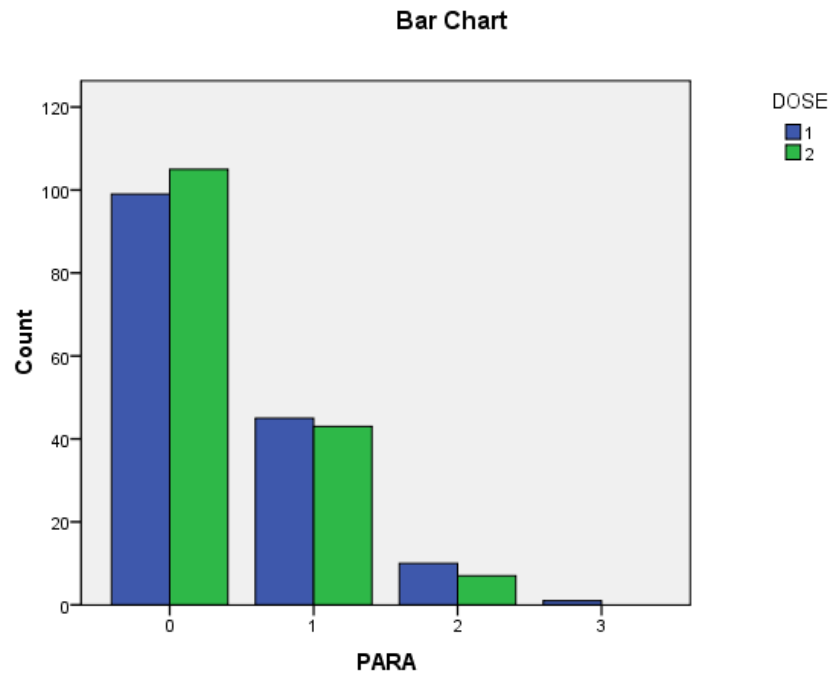
**PREVALENCE OF ASYMPTOMATIC BACTERIURIA-PARITY  
WISE DISTRIBUTION**

			DOSE		
			1-single dose	2-multi dose	Total
PARA	0	Count	99	105	204
		% within DOSE	63.9%	67.7%	65.8%
		% of Total	31.9%	33.9%	65.8%
	1	Count	45	43	88
		% within DOSE	29.0%	27.7%	28.4%
		% of Total	14.5%	13.9%	28.4%
	2	Count	10	7	17
		% within DOSE	6.5%	4.5%	5.5%
		% of Total	3.2%	2.3%	5.5%
	3	Count	1	0	1
		% within DOSE	.6%	.0%	.3%
		% of Total	.3%	.0%	.3%

Nulliparous women are more prone for urinary tract infection.

According to Pearson Chi-Square test, p value is 0.626

## PREVALENCE OF ASYMPTOMATIC BACTERIURIA-PARITY WISE DISTRIBUTION



Nulliparous women are more prone for urinary tract infection.

## **PREVALENCE OF ASYMPTOMATIC BACTERIURIA- TRIMESTER WISE DISTRIBUTION**

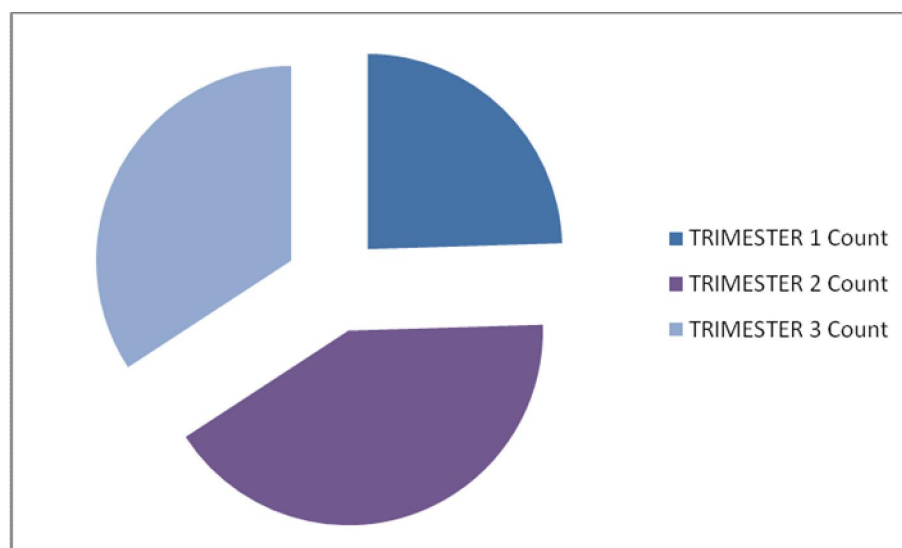
Number of pregnant women in First trimester - 68

Second trimester - 144

Third trimester - 98

Out of 310 antenatal women studied, 68 (21.9%) were found to be in the first trimester, 144 (46.45%) were found to be in the second trimester, 98 (31.61%) were found to be in the third trimester.

### **TRIMESTER WISE DISTRIBUTION**



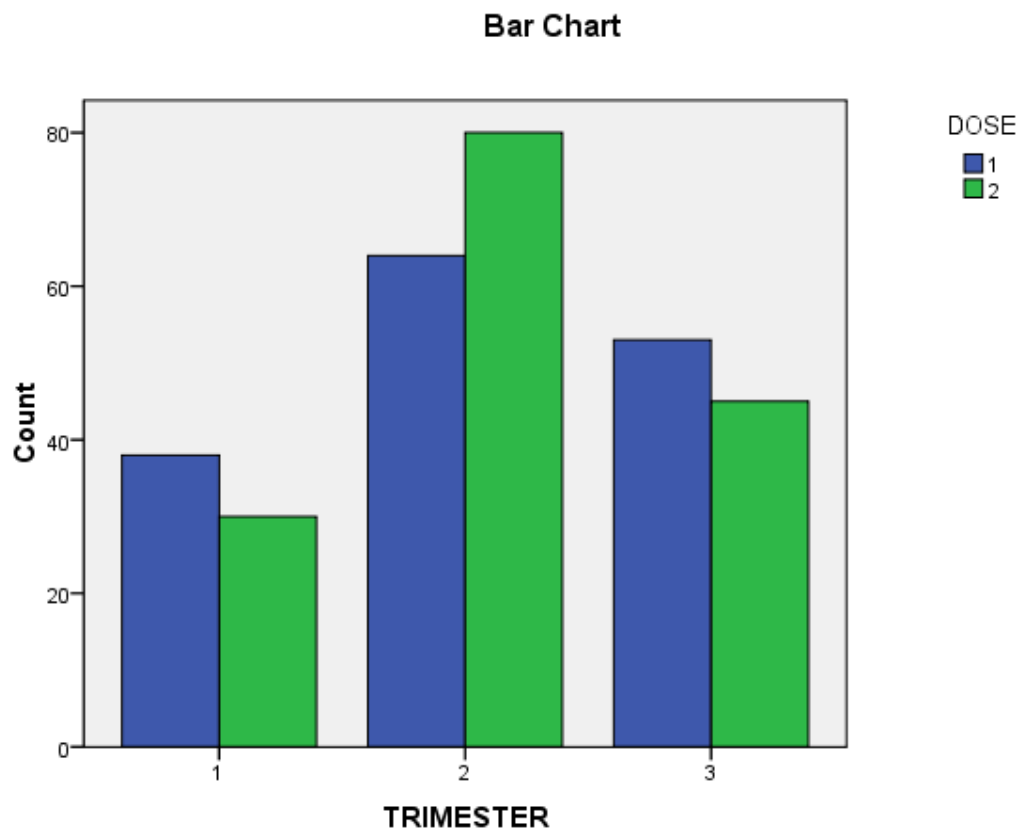
**PREVALENCE OF ASYMPTOMATIC BACTERIURIA-  
TRIMESTER WISE DISTRIBUTION**

			DOSE		
			1-single dose	2-multi dose	Total
TRIMESTER	1	Count	38	30	68
		% within DOSE	24.5%	19.4%	21.9%
		% of Total	12.3%	9.7%	21.9%
	2	Count	64	80	144
		% within DOSE	41.3%	51.6%	46.5%
		% of Total	20.6%	25.8%	46.5%
	3	Count	53	45	98
		% within DOSE	34.2%	29.0%	31.6%
		% of Total	17.1%	14.5%	31.6%

According to Pearson Chi-Square test, p value is 0.185

Asymptomatic bacteriuria is found to be more common in the second trimester followed by third trimester and finally in the first trimester.

## PREVALENCE OF ASYMPTOMATIC BACTERIURIA- TRIMESTER WISE DISTRIBUTION



First trimester - 1

Second trimester - 2

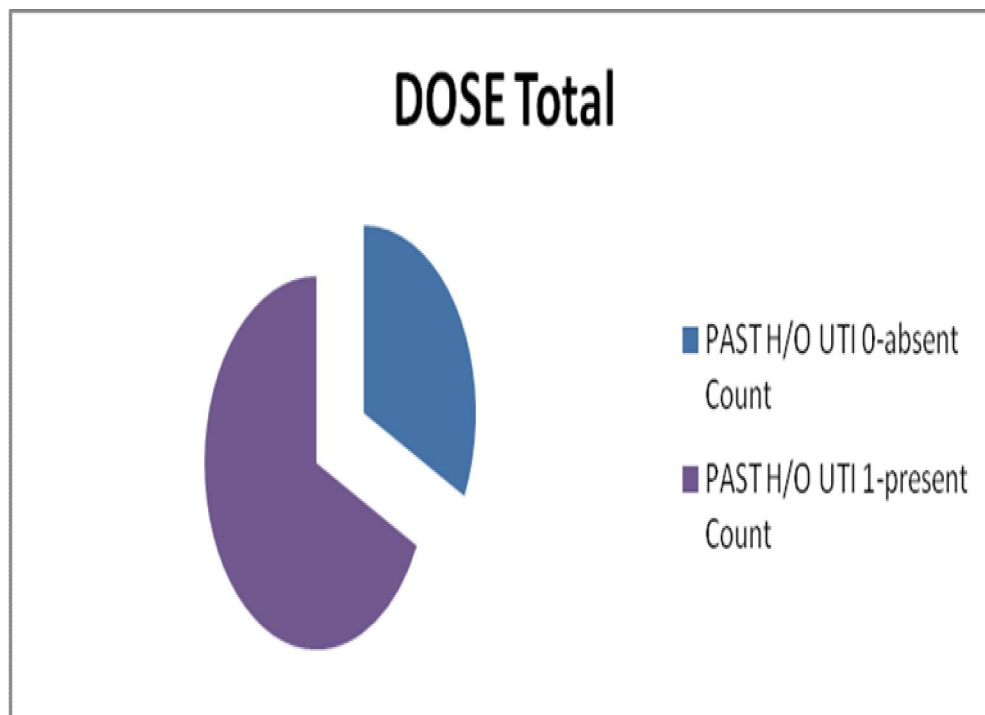
Third trimester – 3

Asymptomatic bacteriuria is found to be more common in the second trimester followed by third trimester and finally in the first trimester.

**PREVALENCE OF ASYMPTOMATIC BACTERIURIA BASED ON  
PAST H/O OF UTI**

PAST H/O UTI PRESENT IN 210

PAST H/O UTI ABSENT IN 100



# **PREVALENCE OF ASYMPTOMATIC BACTERIURIA BASED ON PAST H/O OF UTI**

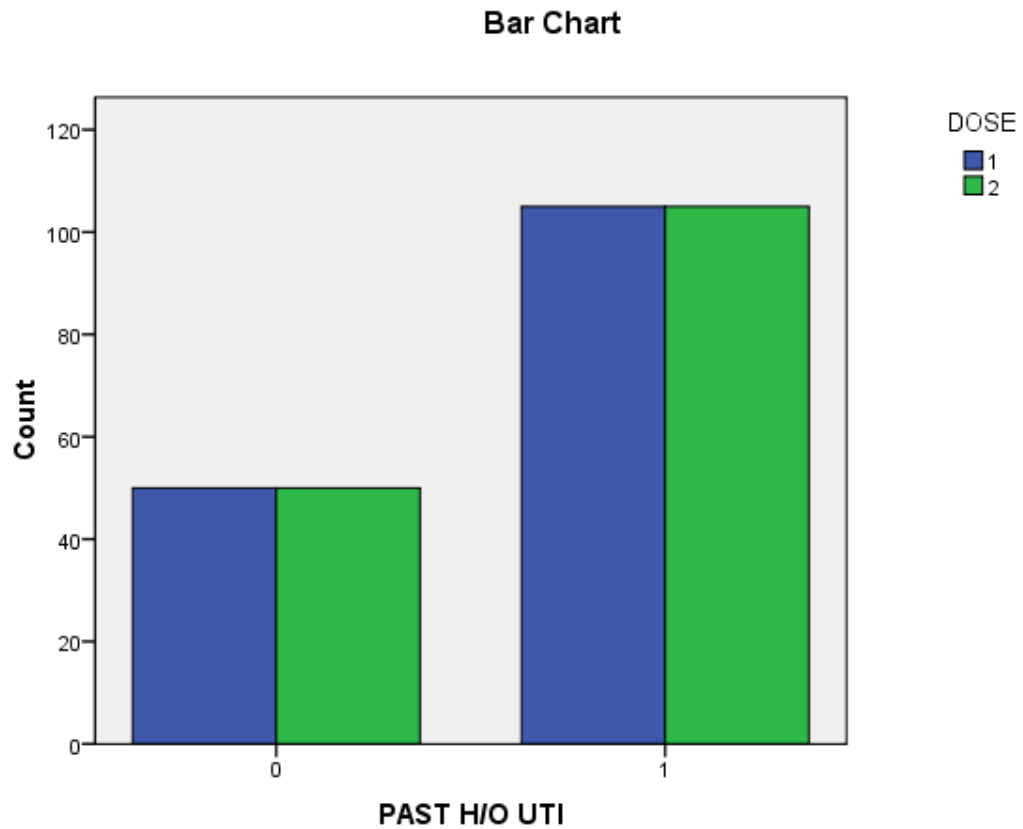
			DOSE		Total
			1-single dose	2-multi dose	
PAST H/O UTI	0-absent	Count	50	50	100
		% within DOSE	32.3%	32.3%	32.3%
		% of Total	16.1%	16.1%	32.3%
	1-present	Count	105	105	210
		% within DOSE	67.7%	67.7%	67.7%
		% of Total	33.9%	33.9%	67.7%

Women having recurrent urinary tract infection are more prone for asymptomatic bacteriuria

According to Pearson Chi-Square test, p value is 1.

Past H/O of UTI is considered to be a significant risk factor for asymptomatic bacteriuria.

# PREVALENCE OF ASYMPTOMATIC BACTERIURIA BASED ON PAST H/O OF UTI



0 – no past H/O UTI

1 – past H/O UTI present

Asymptomatic bacteriuria is more common in women who are having a previous history of infection.



**REPEAT URINE CULTURE IN BOTH-SINGLE DOSE REGIMEN  
AND MULTI DOSE REGIMEN**

			DOSE		
			1-single dose	2-multi dose	Total
RPT URINE C/S	0-No growth	Count	97	113	210
		% within DOSE	62.6%	72.9%	67.7%
		% of Total	31.3%	36.5%	67.7%
	1- Growth	Count	58	42	100
		% within DOSE	37.4%	27.1%	32.3%
		% of Total	18.7%	13.5%	32.3%
	Total	Count	155	155	310
		% within DOSE	100.0%	100.0%	100.0%
		% of Total	50.0%	50.0%	100.0%

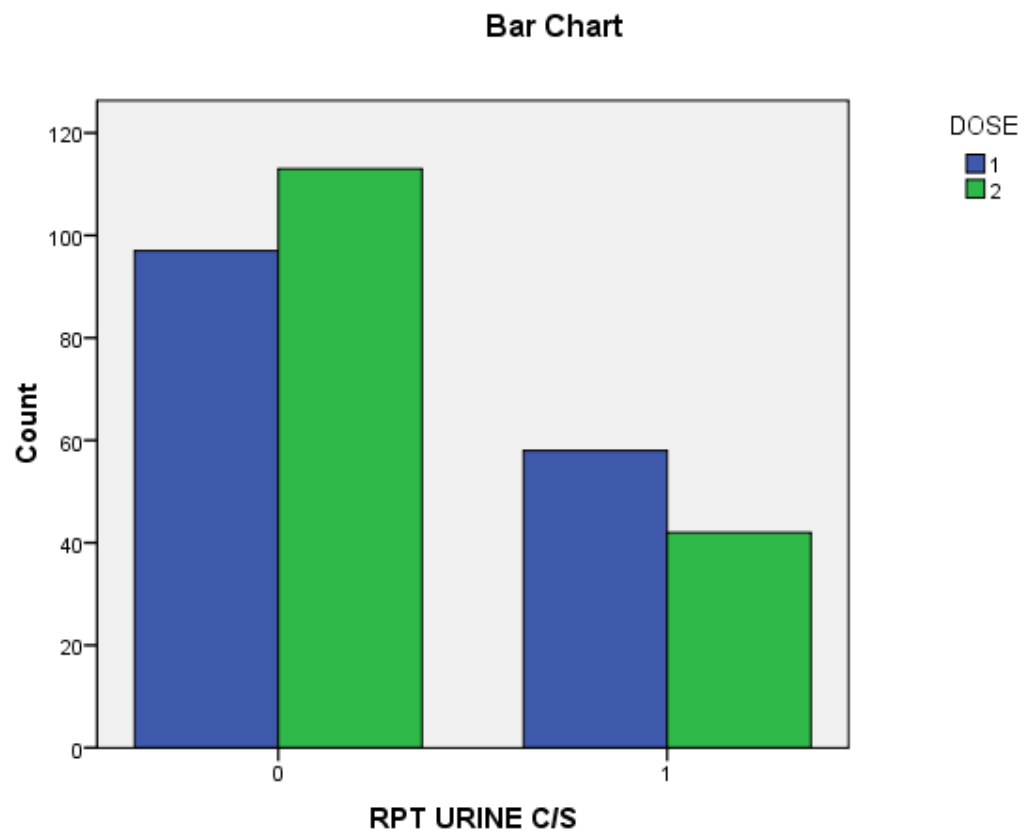
In single dose regimen 62.6% showed no growth in repeat urine culture and 37.4% showed failure of treatment.

In multi dose regimen 72.9% showed no growth in repeat urine culture and 27.1% showed failure of treatment.

According to Pearson Chi-Square test, p value is 0.052

Multi dose regimen is slightly more effective in treating asymptomatic bacteriuria.

## REPEAT URINE CULTURE IN BOTH-SINGLE DOSE REGIMEN AND MULTI DOSE REGIMEN



0 – no growth

1 – presence of growth

Treating bacteriuria plays a major role in eradicating infection.

Moreover, multi dose regimen is more effective in treating bacteriuria

**SIDE EFFECTS COMPARED BETWEEN MULTI DOSE  
REGIMEN AND SINGLE DOSE REGIMEN**

			DOSE		
			1-single dose	2-multi dose	Total
SIDE EFFECTS	0-absent	Count	131	86	217
		% within DOSE	84.5%	55.5%	70.0%
		% of Total	42.3%	27.7%	70.0%
	1-present	Count	24	69	93
		% within DOSE	15.5%	44.5%	30.0%
		% of Total	7.7%	22.3%	30.0%
	Total	Count	155	155	310
		% within DOSE	100.0%	100.0%	100.0%
		% of Total	50.0%	50.0%	100.0%

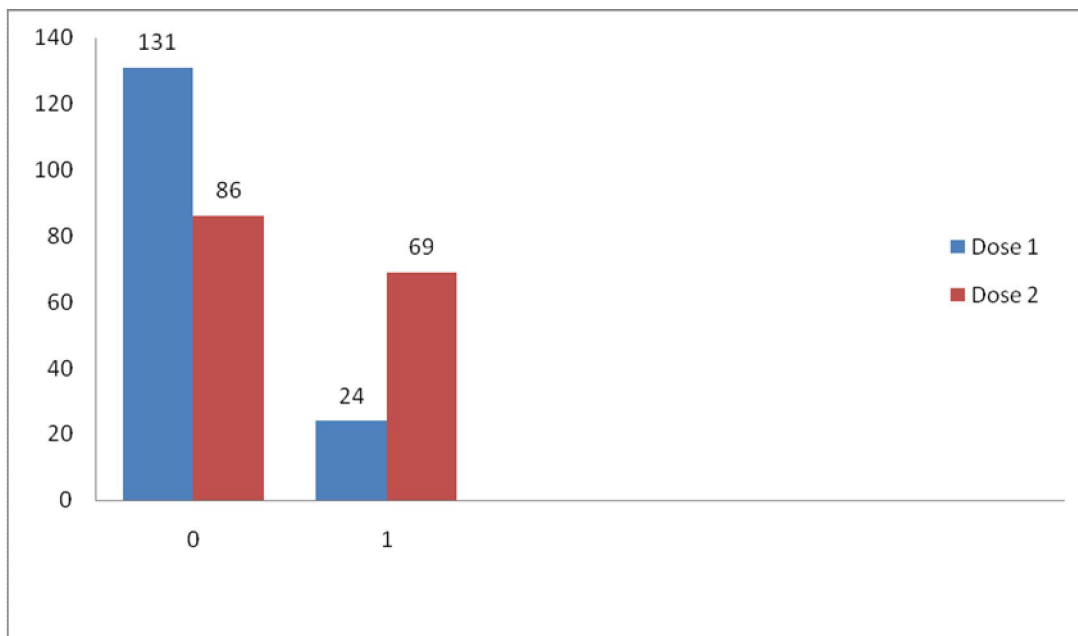
In single dose regimen 84.5% showed no side effects and 15.5% showed few side effects.

In multi dose regimen 55.5% showed no side effects and 44.5% showed few side effects.

According to Pearson Chi-Square test, p value is 0.

Single dose regimen showed reduced incidence of side effects than multi dose regimen.

## SIDE EFFECTS COMPARED BETWEEN MULTI DOSE REGIMEN AND SINGLE DOSE REGIMEN



Dose : 1 – Single dose                      2 – Multi dose

Side effects: 0 – no side effects

1 – presence of side effects

In single dose regimen 84.5% showed no side effects and 15.5% showed few side effects.

In multi dose regimen 55.5% showed no side effects and 44.5% showed few side effects.

Single dose regimen is advantageous in having more safety.

## **DISCUSSION**

Asymptomatic bacteriuria in pregnancy should be given serious regards in terms of maternal and perinatal morbidity. This is a preventable cause by which maternal and perinatal morbidity can be reduced substantially.

Hence, the present study is done to evaluate the effectiveness of single dose and multi dose regimens commonly used in the treatment of bacteriuria in pregnancy. The adverse effects of these regimens is also compared to know the treatment efficacy.

The prevalence of asymptomatic bacteriuria in pregnancy, the risk factors associated and their prevalence is also studied.

The present study included a study group of 310 pregnant women which were randomized and divided equally into two groups, each comprising of 155 pregnant women.

The results were compared with other studies which were already performed and discussed as follows.

Percentage of asymptomatic bacteriuria in antenatal cases were found to be 10.3% in Mitra P. et al (1997), 11.8% in Chng P.K. et al. (1982),

6.8% in Kriplani Alka et al.(1993), 4.7% in Gratacos Eduard et al.(1994), 7.6% in Hagay Zion et al.(1996), 7.0% in Gebre-Selassie S.(1998), 8.4% in Lavanya S V et al.(2002), 10.0% in Priyadarshini Indira et al.(2004) and in our present study(2013) it is 5.16%.

In our study, it was found that 21.61% were in the age group 15-20 yrs, 58.06% were in the age group 21-30 yrs, 12.25% were in the age group 31-35 yrs and 8.06% were in the age group >35 yrs. The prevalence was found to be increased in 21-30 yrs age group. Similar results have been found by Lavanya et al (2002) and Hazhir (2007). But Kass reported an increase in incidence with age.

Stenquist et al (1989) after screening 3254 antenatal women at Sweden came to a conclusion that the risk of bacteriuria in pregnancy increased with increase in gestational age from 0.8% in 12 weeks of gestation to 1.93% at term. In another study by Tugrul et al (2005), the incidence in first, second and third trimesters were 0.9%, 1.83% and 5.6%. In a study in Nigeria, similar results were obtained. In our study, women in the second trimester formed the major group of 46.45%

In our study, 59.03% comprised of primgravidas which was found to be higher than other gravidas. Similar report was obtained by Lavanya et al (2002) .

A study in Vishakapatnam, India revealed that the prevalence of asymptomatic bacteriuria increased as the socioeconomic status of the antenatal women decreased. In our study, maximum women who had asymptomatic bacteriuria belonged to socioeconomic class V (61.29%). This result correlated with studies of Turk M et al. (1962) and Lavanya SV et al. (2002) (66.66%).

In our study, prevalence of asymptomatic bacteriuria in women with past H/O UTI was found to be 67.74%. This report correlated with studies by Chng PK et al. (1982) (23.6%), Maria SC (1999) (18.5%) and Roy SK et al. (1974) (16.1%).

Villar et al. conducted the Cochrane Review to compare the efficacies of various durations for treating asymptomatic bacteriuria. Finally he came to a conclusion that enough evidence was not available to prove if a single-dose and multi-doses were the same in the treatment of asymptomatic bacteriuria.

The relative risk was calculated to assess if the treatment failure for asymptomatic bacteriuria was more for single dose treatment compared to multi dose treatment (RR 1.25, 95% CI 0.93, 1.67). But even then there was no statistical difference. Single-dose treatment showed reduced incidence of side-effects, however (RR 0.52, 95% CI 0.32, 0.85).

In our study the repeat culture showed growth in 37.4% of women who received single dose treatment and in 27.1% of women who received multidose treatment. This is similar to the report obtained previously stating that risk of failure is more in single dose treatment.

Moreover side effects were found to be present in 44.5% of women receiving single dose and in 15.5% of women receiving multi dose treatment. This gives us a report that multi dose was associated with lesser adverse effects.



## SUMMARY

Considering the high incidence of asymptomatic bacteriuria, screening technique definitely has a place in routine antenatal check up. Moreover 25% of these women develop acute pyelonephritis, usually in the third trimester, if left untreated.

Asymptomatic bacteriuria, if recurrent is associated with high incidence of urinary tract abnormality(20%), congenital or acquired.

Ampicillins or cephalosporins are the usual drugs used in the treatment of asymptomatic bacteriuria. Single dose therapy is also suggested.

In this study, though the risk of failure in single dose therapy is more, it is comparable to multi dose therapy. Side effects which occur during single dose treatment is lesser in rate when compared to multi dose therapy, but the difference is not statistically significant.

This study also revealed that

1. The incidence of antenatal women attending antenatal clinic in Government Kilpauk Medical College having asymptomatic bacteriuria is 5.16%.
2. It is more common in 21-30 yrs of age group.

3. It is commoner in Primigravida and occurs more often in second trimester.
4. It is more common in low socioeconomic status. 61.29% of women were in socio economic class V.

## CONCLUSION

Asymptomatic bacteriuria is prevalent in around 2-10% of antenatal women. If it is left untreated, they progress to pyelonephritis late in pregnancy. So early detection and prompt treatment is very important. Moreover it also predisposes to complications like preterm labour and low birth weight infants.

Treating asymptomatic bacteriuria with single dose regimen is almost the same as multi dose therapy, with only a small difference in the failure rate being higher in single dose regimen. The side effects between the two regimens did not show large statistical difference. Moreover there are advantages that, in single dose therapy, there is increased patient compliance, minimal medication, reduced cost and increased safety of the patients.

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Hauth. Rouse.Spong-Section 8-Renal and Urinary Tract Disorders-  
1036-Table 48-1

## PROFORMA

- 1.NAME: OP NO:
- 2.AGE:
- 3.ADDRESS:
- 4.INCOME: OCCUPATION: EDUCATION:
- 5.GRAVIDA: PARA: LIVE: ABORTION:
- 6.LMP: EDD:
- 7.TRIMESTER:
- 8.PAST H/O UTI: PRESENT/ABSENT
- 9.C/O LOWER ABDOMINAL PAIN:
- 10.C/O DYSURIA:
- 11.C/O BURNING MICTURITION:
- 12.C/O FREQUENCY OF MICTURITION:
- 13.URINE C/S-
- ORGANISM:
  - SENSITIVE TO:
- 14.ANTIBIOTIC GIVEN:
- 15.DOSE AND DURATION:
- 16.REPEAT URINE C/S AFTER 1 WEEK-GROWTH: YES/NO
- 17.SIDE EFFECTS:
- YES-SPECIFY-
  - NO

## MASTER CHART

S.NO	NAME	OP. NO	AGE	AGE GROUP	S.E. STATUS	GRAVIDA	PARA	LIVE	ABORTION	TRIM ESTER	PAST H/O UTI	DOSE	RPT URINE C/S	SIDE EFFECTS
											0-ABSENT	1-SINGLE	0-NO GROWTH	0-NO
											1-PRESENT	2-MULTIPLE	1-GROWTH	1-YES
1	Selvakumari	198	19	1	5	1	0	0	0	1	0	1	1	1
2	Vijaya	132	23	2	4	1	0	0	0	2	1	2	0	0
3	Sangeetha	1142	23	2	5	1	0	0	0	2	0	1	0	0
4	Dharani	140	17	1	4	1	0	0	0	3	1	2	1	1
5	Lalitha	1140	27	2	4	1	0	0	0	1	1	1	0	0
6	Vanitha	404	25	2	5	2	1	1	0	3	1	2	0	1
7	Lakshmi	9221	18	1	4	1	0	0	0	2	1	1	1	0
8	Renuka devi	411	26	2	5	2	1	1	0	1	0	2	0	1
9	Ratna	19647	21	2	5	1	0	0	0	1	1	1	0	1
10	Chitra	1587	20	1	4	1	0	0	0	2	1	2	1	1
11	Kuppammal	386	27	2	5	1	0	0	0	3	1	1	0	1
12	Latha	617	21	2	4	1	0	0	0	2	1	2	0	1
13	Kavitha	378	26	2	5	2	1	1	0	1	0	1	1	0
14	Vanthana	377	26	2	4	2	0	0	1	2	1	2	1	0
15	Revathy	293	31	3	5	1	0	0	0	1	1	1	1	0
16	Varalakshmi	361	25	2	5	1	0	0	0	2	1	2	0	0
17	Sasikala	4019	26	2	4	2	0	0	1	2	1	1	0	0
18	Sathya	4061	20	1	5	1	0	0	0	3	1	2	0	0
19	Ammu	347	36	4	4	2	1	1	0	2	1	1	0	0
20	Jeyanthi	339	23	2	5	1	0	0	0	3	1	2	1	0
21	Saraswathi	2068	19	1	5	1	0	0	0	2	1	1	0	0
22	Barkath	4881	26	2	5	2	1	1	0	1	0	2	1	0
23	Shanthi	1928	27	2	3	1	0	0	0	1	1	1	1	0
24	Deepa	1715	18	1	5	1	0	0	0	2	1	2	0	1
25	Uma prakash	1801	30	2	4	1	0	0	0	3	0	1	0	0
26	Vinitha	1915	29	2	4	2	1	1	0	1	0	2	0	1
27	Rebecca	8590	27	2	5	2	1	1	0	1	1	1	1	1
28	Hemavathy	1683	19	1	5	1	0	0	0	2	1	2	0	0
29	Hemalatha	1910	36	4	5	2	1	1	0	1	1	1	0	0
30	Shoba	9312	18	1	5	1	0	0	0	1	0	2	0	1
31	Yogalakshmi	2017	29	2	5	2	1	1	0	3	1	1	0	0
32	Komala	9640	28	2	4	1	0	0	0	1	0	2	1	0
33	Sudha	2069	27	2	4	2	1	0	0	2	1	1	1	0
34	Janaki	9540	19	1	5	1	0	0	0	3	1	2	0	0

35	Nasreen	9514	25	2	5	1	0	0	0	2	1	1	0	0
36	Anushya	9130	32	3	5	2	1	0	0	3	0	2	0	0
37	Panjavarnam	1810	37	4	4	4	3	3	0	1	1	1	1	0
38	Ranjani	1391	28	2	5	3	2	2	0	2	1	2	1	1
39	Sasikala	491	27	2	5	2	1	0	0	1	0	1	0	0
40	Uma	1747	22	2	4	1	0	0	0	1	0	2	0	0
41	Selvarani	1402	21	2	4	2	0	0	1	2	1	1	0	0
42	Tameen	1806	22	2	5	1	0	0	0	2	1	2	0	1
43	Kalpana	1403	33	3	4	2	1	1	0	3	1	2	0	0
44	Usha	1866	18	1	4	1	0	0	0	1	0	1	1	1
45	Naseema	1861	19	1	5	1	0	0	0	2	1	2	0	0
46	Deepika	1814	36	4	5	4	2	2	1	3	1	1	0	0
47	Amudha	284	20	1	4	1	0	0	0	1	1	2	0	0
48	Malliga	4632	20	1	5	1	0	0	0	2	1	1	1	0
49	Prema	2271	26	2	4	3	1	1	1	3	0	1	0	0
50	Uthra	247	28	2	5	3	1	0	1	1	0	2	0	1
51	Uma	3467	30	2	4	2	1	1	0	1	1	1	1	1
52	Julie	3580	18	1	5	1	0	0	0	2	1	1	0	0
53	Jothi	245	25	2	4	1	0	0	0	3	1	2	0	0
54	Vimala	242	19	1	5	1	0	0	0	1	0	1	0	0
55	Amudha	2997	37	4	4	2	1	1	0	2	1	2	0	1
56	Sandhya	191	27	2	5	1	0	0	0	1	1	1	0	0
57	Vandhana	138	17	1	5	1	0	0	0	3	0	2	1	1
58	Selvi	133	32	3	4	3	2	1	0	3	1	1	1	1
59	Rekha	2991	29	2	5	2	1	1	0	3	1	1	1	0
60	Dowlath	10610	22	2	5	1	0	0	0	2	1	1	0	0
61	Anusree	4205	17	1	5	1	0	0	0	1	0	2	0	0
62	Muthulakshmi	206	22	2	5	1	0	0	0	2	1	1	0	0
63	Deepa	202	18	1	4	1	0	0	0	1	0	2	1	1
64	Selvakumari	198	36	4	5	2	1	0	0	1	0	1	0	0
65	Deepa	406	20	1	5	1	0	0	0	2	1	1	1	1
66	Dowlath	10610	28	2	4	1	0	0	0	1	0	2	0	0
67	Durgadevi	417	31	3	5	1	0	0	0	1	0	1	0	0
68	Kanchana	4574	28	2	5	2	1	1	0	1	1	2	0	0
69	Dhanavalli	3980	20	1	5	1	0	0	0	2	1	1	0	0
70	Chaitanya	420	34	3	5	3	2	2	0	3	1	2	0	1
71	Subadra	145	18	1	5	1	0	0	0	2	1	1	1	0
72	Kanmani	859	36	4	4	2	0	0	1	1	0	2	0	0
73	Mathi	30595	23	2	5	1	0	0	0	2	1	1	0	0
74	Sasikala	412	19	1	5	1	0	0	0	2	1	2	0	0
75	Rajeshwari	456	23	2	5	2	1	0	0	3	1	1	1	1
76	Kokila	8246	22	2	5	1	0	0	0	1	0	1	0	0

77	Saraswathi	357	22	2	4	1	0	0	0	3	1	1	0	0
78	Dhanalakshmi	7573	20	1	5	1	0	0	0	3	1	2	0	1
79	Muniyammal	467	32	3	5	2	1	1	0	2	1	2	1	0
80	Varalakshmi	479	20	1	4	1	0	0	0	1	0	1	0	0
81	Rekha	1477	23	2	5	2	0	0	1	2	1	2	0	1
82	Kalyani	482	22	2	5	1	0	0	0	1	1	1	1	0
83	Vanita	483	18	1	5	1	0	0	0	2	1	2	0	0
84	Chitra	4265	26	2	5	2	1	1	0	3	1	1	1	0
85	Deepa	4556	36	4	5	2	1	0	0	1	0	2	0	0
86	Vandhani	377	20	1	5	1	0	0	0	2	1	2	0	0
87	Famidha	4548	33	3	4	2	1	1	0	1	0	1	0	0
88	Dimple	4676	21	2	5	1	0	0	0	2	1	2	1	1
89	Sasikala	490	19	1	4	1	0	0	0	2	0	2	0	0
90	Sarala	5052	23	2	5	1	0	0	0	1	0	1	0	0
91	Manimegalai	513	30	2	4	2	1	1	0	1	0	2	0	1
92	Sumathy	790	22	2	5	1	0	0	0	3	1	1	1	0
93	Saranya	806	24	2	4	2	0	0	1	1	0	2	0	0
94	Shanthi	808	18	1	5	1	0	0	0	1	0	1	0	0
95	Lalitha	801	25	2	5	3	0	0	2	2	0	2	1	0
96	Kuppamma	3113	32	3	4	2	1	1	0	2	1	1	0	0
97	Lakshmi	5020	22	2	5	1	0	0	0	2	1	2	0	0
98	Anastasia	4205	28	2	4	1	0	0	0	3	1	1	1	1
99	Navaneedam	1319	26	2	5	2	1	1	0	3	1	2	0	1
100	Valarmathi	756	36	4	5	2	1	1	0	1	0	1	1	0
101	Umar fathima	766	24	2	5	1	0	0	0	3	1	2	1	0
102	Firdosh begam	4843	23	2	4	1	0	0	0	2	1	1	0	0
103	Suseela	853	20	1	5	1	0	0	0	1	0	2	0	0
104	Jabunisha	94	21	2	5	1	0	0	0	2	0	1	1	1
105	Uma devi	812	22	2	4	1	0	0	0	3	1	2	1	1
106	Sandhya	851	30	2	5	2	1	1	0	3	1	1	1	0
107	Revathy	143	20	1	5	1	0	0	0	1	0	2	0	0
108	Bhuvaneswari	847	31	3	5	2	1	1	0	3	1	1	0	0
109	Mala	173	24	2	5	1	0	0	0	2	1	2	1	0
110	Devi	60	27	2	5	3	1	0	1	1	0	1	0	0
111	Alamelu	828	28	2	4	2	1	1	0	2	1	2	1	1
112	Manonmani	623	19	1	4	1	0	0	0	1	0	1	1	1
113	Devaratchaki	199	25	2	5	1	0	0	0	2	1	1	0	0
114	Usharani	823	32	3	4	2	0	0	1	3	0	2	0	0
115	Julie nithya	266	20	1	5	1	0	0	0	2	1	1	1	1
116	Jeyakodi	267	24	2	4	1	0	0	0	1	1	2	0	0
117	Meera	178	23	2	5	1	0	0	0	2	0	1	0	0
118	Selvi	820	33	3	5	2	1	0	0	1	0	2	1	1

119	Prema	230	21	2	5	1	0	0	0	1	1	1	1	0
120	Velankani	4129	29	2	5	2	1	1	0	2	0	2	0	1
121	Kowsalya	414	28	2	5	1	0	0	0	1	0	1	1	1
122	Malathi	1021	19	1	4	1	0	0	0	2	1	2	0	1
123	Chitra	634	37	4	4	4	2	1	1	1	0	1	0	0
124	Buveshwari	4465	25	2	5	1	0	0	0	3	1	2	0	1
125	Ambika	1254	34	3	4	3	0	0	2	1	0	1	1	1
126	Meena	483	22	2	4	1	0	0	0	2	1	2	0	1
127	Samundiswari	380	32	3	5	2	1	1	0	3	0	1	0	0
128	Karpagam	4846	18	1	5	1	0	0	0	3	1	2	0	1
129	Kavitha	911	33	3	5	2	1	1	0	3	1	1	1	0
130	Deviarasi	898	24	2	5	1	0	0	0	2	1	2	0	1
131	Lavanya	942	34	3	4	3	2	2	0	3	1	1	1	0
132	Rani	939	19	1	4	1	0	0	0	2	1	2	0	0
133	Maragatham	924	23	2	5	1	0	0	0	3	0	1	0	0
134	Kanchana	942	35	3	4	1	0	0	0	2	1	2	0	1
135	Meera	178	23	2	5	1	0	0	0	3	1	1	1	0
136	Nandhini	1842	28	2	5	1	0	0	0	3	0	2	1	1
137	Fathima	2482	27	2	5	2	1	1	0	2	1	1	0	0
138	Radha	8759	35	3	4	1	0	0	0	3	1	2	1	1
139	Bhavani	2932	26	2	4	3	2	1	0	1	0	1	1	0
140	Thenmozhi	245	23	2	4	2	1	0	0	3	0	2	0	0
141	Jeyanthi	339	23	2	5	1	0	0	0	3	0	1	0	0
142	Eshwari	338	22	2	4	1	0	0	0	3	1	1	1	1
143	Muthukutti	334	27	2	4	2	1	1	0	1	0	2	0	1
144	Mohana	331	36	4	5	2	1	0	0	3	1	1	0	0
145	Poongathai	335	23	2	4	1	0	0	0	3	1	2	0	1
146	Sharmila	313	27	2	5	2	1	1	0	2	0	1	0	0
147	Yasodha	3386	32	3	5	1	0	0	0	2	1	2	0	0
148	Vijaya	4106	19	1	4	1	0	0	0	3	1	1	1	1
149	Revathi	293	33	3	5	2	1	1	0	3	1	2	0	1
150	Anish	292	25	2	5	1	0	0	0	2	0	1	0	0
151	Deivani	5107	25	2	5	1	0	0	0	2	1	2	0	1
152	Uma	302	27	2	5	2	1	1	0	3	1	1	1	0
153	Neela	282	25	2	4	1	0	0	0	2	1	2	0	1
154	Ramayee	284	19	1	5	1	0	0	0	3	1	1	0	0
155	Suganya	7354	20	1	4	1	0	0	0	3	1	2	0	1
156	Gnanaselvi	257	25	2	4	3	0	0	2	2	1	1	0	0
157	Amudha	2082	36	4	5	1	0	0	0	3	1	2	0	0
158	Karthiga	1659	20	1	4	1	0	0	0	2	1	1	1	0
159	Ambika	1653	21	2	5	1	0	0	0	2	0	2	0	1
160	Nadiya	1649	26	2	4	2	1	1	0	1	0	1	0	0



161	Dhakshayani	4682	22	2	5	1	0	0	0	2	1	2	0	1
162	Manjula	2312	30	2	4	2	1	1	0	3	1	1	1	0
163	Saritha	1560	29	2	5	3	2	1	0	2	1	2	0	1
164	Umarani	1010	19	1	4	1	0	0	0	2	1	1	0	0
165	Rajeshwari	1342	25	2	4	1	0	0	0	3	1	2	1	1
166	Jayachitra	348	31	3	5	1	0	0	0	2	1	1	0	1
167	Dharani	2537	24	2	4	3	0	0	2	3	0	2	0	1
168	Sathya	1572	29	2	5	2	1	0	0	3	1	1	0	0
169	Anjani	1619	19	1	4	1	0	0	0	3	1	2	0	0
170	Meena	178	28	2	4	2	0	0	1	3	0	1	1	0
171	Kalpana	1412	26	2	5	1	0	0	0	2	1	2	0	1
172	Tasreen	1806	25	2	5	1	0	0	0	2	0	1	0	0
173	Selvarani	1402	38	4	5	3	2	2	0	3	1	2	0	1
174	Ranjani	13891	24	2	4	1	0	0	0	3	1	1	1	1
175	Sasikala	490	22	2	5	1	0	0	0	1	0	2	0	1
176	Uma	7147	31	3	4	2	0	0	1	3	1	2	1	1
177	Selvakumari	198	22	2	5	1	0	0	0	2	1	2	0	0
178	Vijaya	132	22	2	5	1	0	0	0	2	1	1	0	0
179	Sangeetha	1142	19	1	4	1	0	0	0	3	1	1	1	0
180	Dharani	140	32	3	4	2	1	1	0	2	1	2	0	0
181	Lalitha	1141	21	2	5	1	0	0	0	3	0	1	0	0
182	Vanitha	404	27	2	4	1	0	0	0	3	1	2	1	1
183	Lakshmi	9221	20	1	5	1	0	0	0	2	0	1	0	0
184	Renuka	411	26	2	5	1	0	0	0	3	1	2	0	0
185	Rekha	19670	33	3	5	2	1	1	0	2	1	1	1	0
186	Chitra	1587	19	1	4	1	0	0	0	1	0	2	0	0
187	Kuppammal	386	29	2	5	3	1	1	1	3	0	1	0	0
188	Latha	617	33	3	4	2	1	0	0	3	1	1	1	0
189	Kavitha	379	19	1	4	1	0	0	0	2	1	1	0	0
190	Vathana	377	28	2	5	2	1	1	0	2	1	2	0	1
191	Revathy	293	28	2	4	1	0	0	0	3	0	1	0	0
192	Varalakshmi	362	20	1	5	1	0	0	0	2	1	2	0	0
193	Sasirekha	4019	22	2	5	1	0	0	0	2	1	1	1	1
194	Sathya	4061	37	4	5	3	2	1	0	2	1	2	0	0
195	Ammu	354	20	1	5	1	0	0	0	3	1	1	0	0
196	Latha	344	26	2	5	2	1	1	0	1	0	2	1	0
197	Kala	215	25	2	4	1	0	0	0	3	1	1	1	0
198	Geetha	32	19	1	5	1	0	0	0	2	1	2	0	0
199	Saradha	225	19	1	4	1	0	0	0	2	1	1	0	0
200	Kannammal	863	25	2	5	3	1	1	1	1	0	2	0	1
201	Gowri	487	28	2	5	1	0	0	0	3	1	1	1	0
202	Indumathy	8358	24	2	5	2	1	1	0	2	1	2	0	0

203	Suganya	5233	20	1	4	1	0	0	0	3	1	1	0	1
204	Sriranjini	5255	34	3	4	3	1	1	1	2	1	2	0	0
205	Nandini	4542	23	2	5	1	0	0	0	3	1	1	0	0
206	Muniyammal	5546	24	2	4	1	0	0	0	1	0	2	0	0
207	Petchiammal	634	27	2	5	3	2	1	0	3	1	1	1	0
208	Amulu	436	28	2	4	1	0	0	0	2	1	2	1	1
209	Arokiya Mary	345	22	2	5	1	0	0	0	3	1	1	0	0
210	Vandhana	4523	26	2	5	1	0	0	0	3	1	2	0	0
211	Gowthami	224	24	2	4	1	0	0	0	2	1	1	0	0
212	Fathima	323	26	2	5	2	1	1	0	2	1	2	1	0
213	Meenakshi	4764	36	4	4	3	2	0	0	2	1	1	0	0
214	Shanti	365	18	1	5	1	0	0	0	2	1	2	1	1
215	Shobana	3786	28	2	5	2	1	0	0	2	1	1	0	0
216	Kalamani	4856	28	2	4	3	1	1	1	1	0	2	0	0
217	Lalitha	223	19	1	4	1	0	0	0	2	0	1	0	0
218	Mariammal	886	30	2	5	2	0	0	1	2	0	2	0	0
219	Kuzhandai	457	28	2	5	1	0	0	0	2	1	1	0	0
220	Jenny	345	29	2	5	3	1	0	1	3	1	2	0	1
221	Haritha	10355	26	2	5	2	0	0	1	2	0	1	0	0
222	Thamarai	355	24	2	5	1	0	0	0	2	1	2	1	0
223	Sumathy	14291	27	2	5	2	1	0	0	2	1	1	0	0
224	Thenmozhi	1434	24	2	5	1	0	0	0	2	0	2	0	0
225	Nithya	13414	29	2	4	2	1	1	0	2	1	1	0	0
226	Vigneshwari	5754	20	1	5	1	0	0	0	2	1	2	1	1
227	Vinitha	734	25	2	4	1	0	0	0	1	0	1	1	1
228	Polammal	563	26	2	4	2	1	1	0	2	1	1	0	0
229	Vijaya	445	20	1	5	1	0	0	0	2	1	2	0	0
230	Ramalakshmi	2355	24	2	4	1	0	0	0	2	1	1	1	0
231	Madhu	2545	26	2	4	2	1	1	0	2	1	2	0	0
232	Deepika	454	27	2	5	1	0	0	0	3	1	1	1	0
233	Kiruthika	345	28	2	5	2	1	1	0	2	0	2	0	1
234	Kuruvammal	367	22	2	4	1	0	0	0	3	0	1	0	0
235	Pachaiammal	675	23	2	5	2	1	1	0	2	1	1	1	0
236	Thirumani	575	24	2	5	1	0	0	0	3	1	2	1	0
237	Jaya Mary	577	20	1	5	1	0	0	0	3	1	1	0	1
238	Reeta	10453	36	4	5	3	2	1	0	2	1	2	0	0
239	Deepa	354	27	2	4	2	1	1	0	3	1	2	0	0
240	Yuvrani	646	19	1	4	1	0	0	0	2	1	1	0	0
241	Saranya	235	32	3	4	3	1	1	1	3	1	2	1	1
242	Lakshmi	2451	27	2	5	1	0	0	0	2	1	2	0	0
243	Baby	355	18	1	5	1	0	0	0	3	1	1	0	0
244	Jayashree	10355	19	1	5	1	0	0	0	2	0	1	0	0

245	Kaviya	1535	26	2	4	3	1	1	1	2	0	2	0	0
246	Ramya	543	24	2	5	1	0	0	0	3	1	2	1	0
247	Munira begum	234	20	1	5	1	0	0	0	3	1	1	0	0
248	Jayashree	5748	36	4	5	3	1	1	1	2	0	2	1	0
249	Mithra	346	20	1	4	1	0	0	0	1	1	1	1	0
250	Swetha	457	26	2	5	2	1	0	0	3	0	2	1	0
251	Shivashankari	446	28	2	4	1	0	0	0	2	1	1	1	0
252	Sandhiya	545	33	3	4	2	0	0	1	2	1	2	0	1
253	Deepika	756	27	2	5	1	0	0	0	2	0	1	0	0
254	Swetha	10224	26	2	5	2	0	0	1	3	1	2	0	0
255	Sandhiya	546	19	1	4	1	0	0	0	2	1	1	0	0
256	Sandhiya	234	27	2	4	1	0	0	0	3	1	2	1	1
257	Rathi	354	27	2	5	3	2	2	0	2	0	1	0	0
258	Praveena	358	24	2	4	1	0	0	0	2	1	2	0	0
259	Mathumitha	10435	23	2	5	1	0	0	0	3	1	1	0	0
260	Pongkodi	5445	34	3	5	1	0	0	0	2	1	2	0	0
261	Poornima	2547	38	4	5	3	1	0	1	2	1	1	0	0
262	Nisha	2347	20	1	4	1	0	0	0	2	1	2	0	0
263	Charulatha	645	29	2	5	2	1	1	0	3	1	1	0	0
264	Janani	574	22	2	4	1	0	0	0	2	1	2	0	1
265	Madhumitha	564	36	4	5	2	1	0	0	3	1	1	1	0
266	Santhya	10843	20	1	5	1	0	0	0	2	1	2	0	0
267	Vijayalakshmi	1243	21	2	5	1	0	0	0	3	0	1	0	0
268	Hemavathy	4382	22	2	4	1	0	0	0	2	1	2	1	0
269	Kaviya	645	26	2	5	2	1	0	0	3	1	1	0	0
270	Sahina	4435	37	4	5	3	2	2	0	2	0	2	0	1
271	Abinaya	4657	25	2	5	1	0	0	0	2	1	2	0	0
272	Shahina	763	20	1	5	1	0	0	0	2	1	2	0	0
273	Varsha	654	24	2	4	1	0	0	0	3	1	1	0	0
274	Sarmitha	745	35	3	5	3	1	1	1	2	0	2	0	1
275	Jenifier	773	28	2	4	1	0	0	0	1	0	1	0	0
276	Husha	434	36	4	5	3	0	0	2	1	0	2	0	0
277	Divya	346	24	2	5	1	0	0	0	2	1	1	0	0
278	Deniza	3541	20	1	5	1	0	0	0	3	0	2	1	1
279	Rosiz	1538	24	2	4	1	0	0	0	2	1	1	0	0
280	Vennila	15741	36	4	5	1	0	0	0	2	1	2	0	0
281	Kavitha	10595	23	2	4	1	0	0	0	3	1	2	1	0
282	Sharmila	3436	35	3	5	3	1	1	1	1	0	1	1	0
283	Sujithra	464	29	2	5	2	0	0	1	2	1	2	0	1
284	Megala	546	25	2	4	1	0	0	0	3	0	1	0	1
285	Ayesha begam	978	26	2	5	2	1	1	0	2	1	2	1	1
286	Kalpana	844	19	1	5	1	0	0	0	2	1	1	0	0

287	Vasanthi	687	24	2	4	1	0	0	0	3	1	2	0	0
288	Kavitha	868	32	3	5	2	1	1	0	1	0	2	0	0
289	Asma	467	38	4	5	4	0	0	3	2	1	1	1	1
290	Ebinesan	582	23	2	5	1	0	0	0	2	1	2	0	1
291	Pavitra	435	30	2	4	2	1	1	0	1	0	1	0	0
292	Archana	352	30	2	5	2	1	1	0	2	0	2	0	0
293	Subha latha	2328	26	2	5	1	0	0	0	2	1	2	0	1
294	Satherna	1863	28	2	4	3	2	2	0	2	1	1	0	0
295	Malalthy	12121	32	3	5	2	0	0	1	2	1	2	0	0
296	Furzana	1265	27	2	5	1	0	0	0	2	1	1	1	0
297	Fazila	356	24	2	5	1	0	0	0	1	0	2	1	0
298	Durgadevi	724	33	3	4	3	1	1	1	2	0	2	0	1
299	Vaishnavi	235	26	2	4	1	0	0	0	2	1	1	0	0
300	Esther	10283	36	4	5	2	1	1	0	1	0	1	0	0
301	Sanjana	1284	28	2	5	2	1	0	0	2	1	1	1	0
302	Nanthitha	1082	31	3	4	1	0	0	0	2	1	2	1	0
303	Yamini	1246	32	3	3	2	1	1	0	3	0	2	0	1
304	Hemavathy	1234	32	3	4	2	1	1	0	2	1	2	0	0
305	Reshma	12354	27	2	5	1	0	0	0	1	0	1	0	0
306	Valarmathy	375	28	2	4	2	1	0	0	2	1	1	0	0
307	Yuvashree	3588	23	2	5	1	0	0	0	3	1	2	1	1
308	Ramya	478	33	3	5	3	2	2	0	2	1	1	1	0
309	Santhiya	436	38	4	5	4	1	1	2	2	0	2	1	0
310	Pavithra	3664	22	2	4	1	0	0	0	2	1	2	0	0

ETHICAL COMMITTEE  
GOVT. KILPAUK MEDICAL COLLEGE, KILPAUK,  
CHENNAI- 10.

Venue: PANAGAL HALL, KMC  
Dt: 01.02.2011

CHAIRPERSON

Prof. Dr. V. KANAGASABAI, MD.,  
Dean

Govt. Kilpauk Medical College, Chennai-10

Sub: Ethical Committee project work - approved – regarding.

Ref: Lr.No.3944/Audit/E1/09 Dt. 30.11.2010

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With above reference, the Institutional Ethical committee meeting for the following students was conducted at our Institution on 01.02.2011.

S.NO.	Name	Topic
1.	Dr.Navin Kumar, MS(Ortho), PG., Govt. Royapettah Hospital, Chennai.	1.To Identify a Safe Zone to approach proximal Humerus 2.To study Anatomical relations of Axillary nerve, its course & its Variations
2.	Dr.T.Satheesh Kumar, D.Ortho., PG., Govt. Royapettah Hospital, Chennai	Hereditary Multiple Exostosis
3.	Dr.J. Jeya Shambavi, MD(Pathology), PG., Kilpauk Medical College, Chennai-10	Clinicopathological Histomorphological and Immunohistochemical Study of Neuroendocrine Tumors of GIT
4.	Dr.L. R. Saranya. MD., (Paed.)PG., Kilpauk Medical College, Chi-10	Cord Blood Zinc Level in Term-Small for Gestational Age Neonates
5.	Dr.A.Satheesh Kumar, MS(ENT), PG., Kilpauk Medical College, Chennai	Study on Cases of Chronic Suppurative Otitis Media in Tubo Tympanic Type Due to Sinusitis as Focal Sepsis
6.	Dr.R.Parthiban,(Msc.,Physiology), PG., Kilpauk Medical College,Ch-10	Prevalence of Cardiac Dysautonomia in Type I Diabetes mellitus
7.	B. Manikandan, (Msc., Physiology), PG., Kilpauk Medical College, Chennai-10	A Comparative Study of Left Ventricular Structure and Function in Obese and Non Obese Subjects
8.	G. Selvakumar, (MSc., Physiology), PG., Kilpauk Medical College, Chennai-10	A Study of the Intraocular Pressure In Patients with Diabetic Normotensive, Diabetic Hypertensive and Normal Subjects

9.	R. Ragulji, (Msc., Physiology), PG., Kilpauk Medical College, Ch-10	A Study of Pulmonary function in insulin dependent diabetes mellitus
10.	V.M. Jenila Vemy, (Msc., Physiology), PG., Kilpauk Medical College, Chennai-10	Cardiovascular Autonomic Dysfunction in Chronic Kidney Disease
11.	Dr.G. Lakshmi, MD(O&G), PG., Kilpauk Medical College, Ch-10	A Study of Association of Thyroid Disorders in Abnormal Uterine Bleeding
12.	Dr.R. Harini, MD(O&G), PG., Kilpauk Medical College, Chennai	Single Dose Antibacterial treatment for Asymptomatic Bacteriuria in Pregnancy
13.	Dr.E.Geetha, MD(O&G), PG., Kilpauk Medical College, Chennai	A Study of the incidence course of Pregnancy and Pregnancy outcome in Obstetric Cholestasis and to evaluate the efficiency of UDCA in relieving the Symptoms and Improving the Perinatal outcome in these Patients
14.	Dr.S. Nithya, MD(O&G), PG., Kilpauk Medical College, Chennai	Prospective Study of Prevalence of diabetes Mellitus, Thyroid Dysfunction and Hyperprolactinemia in Recurrent Pregnancy loss
15.	Dr.Mohideen Fathima, MD(O&G), PG., Kilpauk Medical College, Chennai	A Study of evaluation of multi system changes in Gestational hypertension / severe pre-eclampsia/eclampsia patients
16.	Dr.M.Padma Priya, MD(O&G), PG., Kilpauk Medical College, Chennai	Dyslipidemia – as a Predictor of PIH
17.	Mrs.G. Savitha, (Msc., Medical Bio Chemistry), Kilpauk Medical College, Chennai-10	Association of subclinical hypothyroidism in metabolic syndrome patients
18.	Dr.K. Bharadhwaj, MD(G.M.), PG., Kilpauk Medical College, Ch-10	A Study on Peripheral Vascular Disease in Type 2 Diabetes Mellitus
19.	Dr.B.Priya, MD(G.M.), PG	Study of Serum Bilirubin Concentration in Established Coronary Artery Disease
20.	Dr.R.Hema, MD(G.M.), PG.,	Study of Troponin I level in Supraventricular Tachycardia in Non Cad Patients
21.	Dr.P.Manoj Kumar, MD(G.M.), PG., Kilpauk Medical College, Ch-10	A Study on Pulmonary Functions in Type 2 Diabetes Mellitus
22.	Dr.M.Dhanasekar, MD(G.M.), PG.,	Prognostic Risk Stratification of Acute Coronary Syndrome – Role of Highly Sensitive – Reactive Protein
23.	Dr.N. Karthik, MD(G.M.), PG., Kilpauk Medical College, Chennai-10	A Study of Comparison of QT Dispersion in Acute Myocardial Infarction Between Early Reperfusion and Late Reperfusion Therapy

24.	Dr.H. Anuradha, MD(G.M.), PG, Kilpauk Medical College, Ch-10	A Study of Stress Hyperglycemia in Moderate Degree Burns
25	Dr. V. Nandakumar, MD(G.M.), PG.,	A Prospective Study of Clinical Profile of Emphysematous Pyelonephritis in Type Two Diabetes Mellitus
26.	Dr.S.Sasikumar, MS(G.S.), PG., Govt. Royapettah Hospital, Chennai	A Study of Unusual Presentations of Appendicitis.
27.	Dr.S.R.Padmanabham, MS(GS), PG., Govt. Royapettah Hospital, Chennai	A Comparative Study Between Autologous Platelet Rich Plasma and Saline Dressing for Diabetic Ulcer
28.	Dr.C.Rose, Scientist-G and Head, Biotechnology, Central Leather Institute, Chennai.	Wound healing efficacy of the chitosan —containing collagenous biomaterial on burn wound
29.	E.K. Lavanya,B.Tech, Biotechnology, PG., Prathyusha Institute of Technology and Management, Tiruvallur.	Isolation and Characterization of Bacterial Pathogens from Eye Infection

We are glad to inform you that at the Ethical Committee meeting, the documents were discussed and the above short term projects are Ethically approved.

  
CHAIRPERSON  
DEAN

Govt. Kilpauk Medical College,  
Chennai-10.

To: The Individuals

## சுய ஒப்புதல் படிவம்

ஆய்வு செய்யப்படும் தலைப்பு :  
 மகளிர் மற்றும் மகப்பேறு மருத்துவத்துறை :  
 கீழ்ப்பாக்கம் மருத்துவக்கல்லூரி :  
 பங்கு பெறுபவரின் பெயர் :  
 பங்கு பெறுபவரின் வயது :  
 பங்கு பெறுபவரின் எண் :

பங்கு பெறுபவர் இதனை (✓) குறிக்கவும்.

- ❖ மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும் அதற்கான தகுந்த விளக்கங்களை கேட்க வாய்ப்பளிக்கப்பட்டுள்ளது என அறிந்து கொண்டேன். ☐
- ❖ நான் இவ்வாய்வில் தன்னிச்சையாகத் தான் பங்கேற்கிறேன்.எந்த காரணத்தினாலோ எந்த சட்டசிக்களுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகிக் கொள்ளலாம் என்றும் அறிந்து கொண்டேன்.ஒ ☐
- ❖ இந்த ஆய்வு சம்பந்தமாகவோ அதை சார்ந்து மேலும் ஆய்வு மேற்கொள்ளும் போது இந்த ஆய்வில் பங்கு பெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். ☐
- ❖ இந்த ஆய்வின் மூலம் கிடைக்கும் தகவலையோ முடிவையோ பயன்படுத்திக் கொள்ள மறுக்கமாட்டேன். ☐
- ❖ இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக் கொள்கிறேன். இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உன்மையுடன் இருப்பேன் என்றும் உறுதியளிக்கிறேன். ☐
- ❖ இந்த ஆய்வில் ஒருமுறை 5 மி இரத்த பரிசோதனைக்காக எடுத்தக் கொள்ளப்படும் என்பதை அறிவேன்.

பங்கேற்பவரின் கையொப்பம் \_\_\_\_\_  
 இடம் \_\_\_\_\_ தேதி \_\_\_\_\_

பங்கேற்பவரின் பெயர் மற்றும் விலாசம்  
 சாட்சியாளரின் கையொப்பம்

இடம் \_\_\_\_\_ தேதி \_\_\_\_\_  
 சாட்சியாளரின் பெயர் மற்றும் விலாசம்

ஆய்வாளரின் கையொப்பம்  
 இடம் \_\_\_\_\_ தேதி \_\_\_\_\_  
 ஆய்வாளரின் பெயர் \_\_\_\_\_